DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 416, 418, 441, 460, 482, 483, 484, 485, 486, 488, 491, and 494

[CMS–3346–P]

RIN 0938–AT23

Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would reform Medicare regulations that are identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers. This proposed rule would increase the ability of health care professionals to devote resources to improving patient care by eliminating or reducing requirements that impede quality patient care or that divert resources away from furnishing high quality patient care.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 19, 2018.

ADDRESSES: In commenting, please refer to file code CMS–3346–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3346–P, P.O. Box 8010, Baltimore, MD 21244–1810.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3346–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Alpha-Banu Wilson, (410) 786–8687. We have also included a subject matter expert under the ''Provisions of the Proposed Rule'' section for each provision set out in the proposed rule.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents.

I. Executive Summary and Background

A. Purpose

Over the past several years, we have revised the Conditions of Participation (CoPs) and Conditions for Coverage (CfCs) to reduce the regulatory burden on providers and suppliers while preserving health and safety. We identified obsolete and burdensome regulations that could be eliminated or reformed to improve effectiveness or reduce unnecessary reporting requirements and other costs, with a particular focus on freeing up resources that health care providers, health plans, and States could use to improve or enhance patient health and safety. We also examined policies and practices not codified in rules that could be changed or streamlined to achieve better outcomes for patients while reducing burden on providers and suppliers of care, and we identified non-regulatory changes to increase transparency and to become a better business partner. In addition, the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) have reaffirmed their commitment to the vision of creating an environment where agencies incorporate and integrate the ongoing retrospective review of regulations into Department operations to achieve a more streamlined and effective regulatory framework. The objectives were to improve the quality of existing regulations consistent with statutory requirements; streamline procedural solutions for businesses to enter and operate in the marketplace; maximize net benefits (including benefits that are difficult to quantify); and reduce costs and other burdens on businesses to comply with regulations.

In accordance with these goals, we published three final rules that identified unnecessary, obsolete, or excessively burdensome regulations on health care providers, suppliers, and beneficiaries. These rules further increased the ability of health care professionals to devote resources to improving patient care by eliminating or reducing requirements that impede quality patient care or that divert providing high quality patient care:

- ''Reform of Hospital and Critical Access Hospital Conditions of Participation'', published May 16, 2012 (77 FR 29034);
- ''Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction'', published May 16, 2012 (77 FR 29002) and;
- ''Regulatory Provisions to Promote Program Efficiency, Transparency, and

Burden Reduction; Part II'', published May 12, 2014 (79 FR 27105).

This proposed rule is a continuation of our efforts to reduce regulatory burden and is in accordance with the January 30, 2017 Executive Order ''Reducing Regulation and Controlling Regulatory Costs'' (Executive Order 13771). We propose changes to the current requirements, CoPs, and Conditions for Coverage (CfCs) that will simplify and streamline the current regulations and thereby increase provider flexibility and reduce excessively burdensome regulations, while also allowing providers to focus on providing high-quality healthcare to their patients. This proposed rule will also reduce the frequency of certain required activities and, where appropriate, revise timelines for certain requirements for providers and suppliers and remove obsolete, duplicative, or unnecessary requirements. Ultimately, these proposals balance patient safety and quality, while also providing broad regulatory relief for providers and suppliers.

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on Medicare and Medicaid participating providers and suppliers and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork'' Initiative, we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to Requests for Information (RFIs) that were included in the 2017 prospective payment regulations for most provider types. We refer readers to the public comments that were submitted in response to the RFI for the following 2017 payment regulations:

- End-Stage Renal Disease Prospective Payment System and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program found at *https://www.regulations.gov/docket?D=CMS-2017-0084.*
- CY 2018 Home Health Prospective Payment System Rate Update; Value-Based Purchasing Model; and Quality Reporting Requirements found at *https://www.regulations.gov/docket?D=CMS-2017-0100.*
- FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality found at *https://www.regulations.gov/document?D=CMS-2017-0062-0001.*
- FY 2018 Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System RFI, found at *https://www.regulations.gov/docket?D=CMS-2017-0055.*
- CY 2018 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates found at *https://www.regulations.gov/docket?D=CMS-2017-0091.*
- FY 2018 Inpatient Rehabilitation Facility Prospective Payment System found at *https://www.regulations.gov/document?D=CMS-2017-0059-0002.*
- FY 2018 Inpatient Psychiatric Facilities Prospective Payment System found at *https://www.regulations.gov/document?D=CMS-2018-0053-0002.*
- CY 2018 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B found at *https://www.regulations.gov/docket?D=CMS-2017-0092.*
- FY 2018 Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities found at *https://www.regulations.gov/document?D=CMS-2017-0060-0002.*

Public comments on the RFIs can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation dockets on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

B. Summary of Major Provisions

We propose to reduce regulatory burden on providers and suppliers by modifying, removing, or streamlining current regulations that we now believe are excessively burdensome. The proposals fall under three categories: (1) Proposals that simplify and streamline processes, (2) proposals that reduce the frequency of activities and revise timelines, and (3) proposals that are obsolete, duplicative, or that contain unnecessary requirements, as follows.

1. Proposals That Simplify and Streamline Processes

a. Discharge Planning in Religious Nonmedical Health Care Institutions (RNHCIs)

We have concluded that a more condensed and flexible process for discharge planning for RNHCIs would reduce burden and simplify the discharge process for patients. Specifically, we propose to revise the requirements at 42 CFR 403.736(a), requiring an evaluation, and § 403.736(b), requiring a discharge plan. Instead of specifying detailed discharge processes, we would simply require RNHCIs to assess the need for a discharge plan for any patient identified as likely to suffer adverse consequences if there is no plan, and provide discharge instructions to the patient and the patient's caregiver as necessary when the patient is discharged home.

b. Ambulatory Surgical Center (ASC): Transfer Agreements With Hospitals

We propose to remove the requirements at 42 CFR 416.41(b)(3), ''Standard: Hospitalization.'' This would address the competition barriers that currently exist in some situations where hospitals providing outpatient surgical services refuse to sign written transfer agreements or grant admitting privileges to physicians performing surgery in an ambulatory surgical center (ASC). The Emergency Medical Treatment and Labor Act emergency response regulations would continue to address emergency transfer of a patient from an ASC to a nearby hospital.

c. ASC Requirements for Comprehensive Medical History and Physical Assessment

We propose to remove the current requirements at § 416.52(a) and replace them with requirements that defer, to a certain extent, to the ASC policy and operating physician's clinical judgment to ensure that patients receive the appropriate pre-surgical assessments tailored to the patient and the type of surgery being performed. We still would require the operating physician to document any pre-existing medical conditions and appropriate test results, in the medical record, which would have to be considered before, during and after surgery. In addition, we have retained the requirement that all pre-surgical assessments include documentation regarding any allergies to drugs and biologicals, and that the medical history and physical examination (H&P), if completed, be

placed in the patient's medical record prior to the surgical procedure.

d. Hospice Requirements for Medication Management

We have concluded that the requirements at 42 CFR 418.106(a)(1), related to having on the hospice staff, an individual with specialty knowledge of hospice medications, is no longer necessary for various reasons. Therefore, we propose to remove these requirements.

In addition, we propose to replace the requirement that hospices provide a copy of medication policies and procedures to patients, families and caregivers with a requirement that hospices provide information regarding the use, storage, and disposal of controlled drugs to the patient or patient representative, and family. This information would be provided in a more user-friendly manner, as determined by each hospice. We believe this could improve patients' and caregivers' comprehension and maximize the effectiveness of the education effort.

e. Hospice Requirements: Orientation of Skilled Nursing Facility (SNF) and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICF/IID) Staff

We propose to move the requirements at § 418.112(f) to the ''Written agreement'' standard at new § 418.112(c)(10). Moving the requirement for facility staff orientation from a standalone requirement that places responsibility solely on hospices to the section of the rule related to the written agreement established between hospices and skilled nursing facilities (SNFs) and intermediate care facilities for individuals with intellectual disabilities (ICFs/IID) will allow both entities to negotiate the terms for assuring orientation of facility staff. This will give hospices more freedom to develop innovative approaches and avoid effort duplication with other hospices that are orienting the same facility staff.

f. Hospital Quality Assessment and Performance Improvement Program (QAPI Program)

We propose a new standard at 42 CFR 482.21(f), ''Unified and integrated QAPI program for multi-hospital systems.'' We would allow a hospital that was part of a hospital system consisting of multiple separately certified hospitals using a system governing body that was legally responsible for the conduct of two or more hospitals, the system governing body could elect to have a unified and integrated Quality Assessment and Performance Improvement (QAPI) program for all of its member hospitals after determining that such a decision was in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital within the system would have to demonstrate that: The unified and integrated QAPI program was established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and the unified and integrated QAPI program would establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, were given due consideration, and that the unified and integrated QAPI program would have mechanisms in place to ensure that issues localized to particular hospitals were duly considered and addressed.

g. Hospital Requirements for Comprehensive Medical History and Physical Examinations (§§ 482.22, 482.24, and 482.51)

We propose to allow hospitals the flexibility to establish a medical staff policy describing the circumstances under which such hospitals could utilize a pre-surgery/pre-procedure assessment for an outpatient, instead of a comprehensive medical history and physical examination (H&P). We believe that the burden on the hospital, the practitioner, and the patient could be greatly reduced by allowing this option. In order to exercise this option, a hospital would need to document the assessment in a patient's medical record. The hospital's policy would have to consider patient age, diagnoses, the type and number of surgeries and procedures scheduled to be performed, comorbidities, and the level of anesthesia required for the surgery or procedure; nationally recognized guidelines and standards of practice for assessment of specific types of patients prior to specific outpatient surgeries and procedures; and applicable state and local health and safety laws.

h. Hospital Infection Control Program

We propose a new standard at § 482.42(c), ''Unified and integrated infection control program for multi-hospital systems.'' Like the proposed requirements for a unified and integrated QAPI program, the proposed standard for infection control would allow a hospital that is part of a hospital system consisting of multiple separately certified hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have a unified and integrated infection control program for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital within the system must demonstrate that: The unified and integrated infection control program is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; the unified and integrated infection control program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated infection control program has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed; and a qualified individual (or individuals) has been designated at the hospital as responsible for communicating with the unified infection control program and for implementing and maintaining the policies and procedures governing infection control as directed by the unified infection control program.

i. Special Requirements for Psychiatric Hospitals

We propose at § 482.61(d) to clarify the scope of authority for non-physician practitioners or Doctor of Medicine Doctor of Osteopathic Medicine (MD/DOs) to document progress notes of patients receiving services in psychiatric hospitals.

j. Special Requirement for Transplant Centers and Definitions

We are proposing a nomenclature change at part 482 and the transplant center regulations at §§ 482.68, 482.70, 482.72 through 482.104, and at § 488.61. This change would update the terminology used in the regulations to conform to the terminology that is widely used and understood within the transplant community, thereby reducing provider confusion.

k. Data Submission, Clinical Experience, and Outcome Requirements for Re-Approval of Transplant Centers

We propose to remove the requirements at § 482.82 that require transplant centers to submit clinical experience, outcomes, and other data in order to obtain Medicare re-approval. Transplant centers will still be required to comply with the CoPs at §§ 482.72 through 482.104 and the data submission, clinical experience, and outcome requirements for initial Medicare approval under § 482.80.

l. Special Procedures for Approval and Re-Approval of Organ Transplant Centers

We propose to remove the requirements at § 488.61(f) through (h) with respect to the re-approval process for transplant centers. This change corresponds to the proposed removal of the provisions § 482.82.

m. HHA Requirements for Verbal Notification of Patient Rights and Responsibilities

We propose to remove the requirements for verbal (meaning spoken) notification of patient rights to those patient rights elements for which the Social Security Act (the Act) requires such verbal notification. Specifically, we propose to only require verbal notice for those rights related to payments made by Medicare, Medicaid, and other federally funded programs, and potential patient financial liabilities.

n. Personnel Requirements for Portable X-Ray Technologists

We propose to revise § 486.104, ''Condition for coverage: Qualifications, orientation and health of technical personnel'', to align the current requirements at § 486.104(a)(1), (2), (3), (4) with § 482.26(c)(2), which refers to qualifications of radiologic technologists in hospitals and is focused on the qualifications of the individual performing services.

o. Portable X-Ray Requirements for Orders

We propose to revise the requirements for portable x-ray orders at § 486.106(a)(2). We propose to remove the requirement that physician or non-physician practitioner's orders for portable x-ray services must be written and signed. We also propose to replace the specific requirements related to the content of each portable x-ray order with a cross-reference to the requirements at 42 CFR 410.32, which also apply to portable x-ray services. These proposed changes would simplify the ordering process for portable x-rays and promote the use of more efficient ordering methods, such as electronic orders.

p. Emergency Preparedness Requirements: Requirements for Emergency Plans

We propose to eliminate part of the requirement from § 482.15(a)(4) for hospitals and other parallel provisions for other affected Medicare and Medicaid providers and suppliers (referred to collectively as ''facilities,'' throughout the remainder of this proposed rule where applicable), that facilities document efforts to contact local, tribal, regional, State, and Federal emergency preparedness officials, and that facilities document their participation in collaborative and cooperative planning efforts. In accordance with the remaining requirement at § 482.15(a)(4), facilities would still be required to include a process for cooperation and collaboration with local, tribal, regional, State and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation. Only the documentation requirements would be eliminated.

2. Proposals That Reduce the Frequency of Activities and Revise Timelines

a. Home Health Agency (HHA) Requirements for Providing Patients With Copies of Clinical Records

We propose to remove the requirement that Home Health Agencies (HHAs) provide a copy of the clinical record to a patient, upon request, by the next home visit. We propose to retain the requirement that the copy of the clinical record must be provided, upon request, within 4 business days.

b. CAH Annual Review of Policies and Procedures

We propose to change the requirement at § 485.635(a)(4) to reflect the current medical practice where providers are expected to update their policies and procedures as needed in response to regulatory changes, changes in the standard of care, or nationally recognized guidelines. The current CoP at § 485.635(a)(4) requires a CAH's professional personnel to review its policies at least annually and the CAH to review as necessary. We propose to reduce burden and provide flexibility by requiring the CAH's, professional personnel, at a minimum, to conduct a biennial review of its policies and procedures instead of an annual review.

c. Comprehensive Outpatient Rehabilitation Facility (CORF) Utilization Review Plans

We propose to amend the utilization review plan requirements at § 485.66 to reduce the frequency of utilization reviews from quarterly to annually. This would allow an entire year to collect and analyze data to inform changes to the facility and the services provided.

d. Community Mental Health Center (CMHC) Requirements for Updating the Client Assessment

We propose to remove the requirement that all Community Mental Health Center (CMHC) clients receive an updated assessment every 30 days. Instead, we would require updates of the patient assessment in accordance with client needs and standards of practice. For clients receiving partial hospitalization services, we propose to retain the 30 day assessment update time frame in accordance with existing Medicare payment requirements for partial hospitalization services.

e. RHC and FQHC Review of Patient Care Policies

We propose to revise the requirement at § 491.9(b)(4) that RHC and FQHC patient care policies are reviewed at least annually by a group of professional personnel to review every other year to reduce the frequency of policy reviews.

f. RHC and FQHC Program Evaluation

We propose to revise the requirement at § 491.11(a) by changing the frequency of the required RHC or FQHC evaluation from annually to every other year.

g. Emergency Preparedness Requirements: Requirements for Annual Review of Emergency Program

On September 16, 2016, we finalized a rule imposing emergency preparedness requirements on most Medicare and Medicaid facilities (Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 81 FR 63860). Facilities participating in Medicare and/or Medicaid are now required, among other things, to review their emergency preparedness programs annually. This includes a review of their emergency plans, policies and procedures, communication plans, and training and testing programs. We propose to revise these requirements, so that applicable providers and suppliers have increased flexibility with compliance.

h. Emergency Preparedness Requirements: Requirements for Training

As with the review of the emergency plan previously discussed, we propose to revise the requirement that facilities develop and maintain a training program based on the facility's emergency plan annually. Instead, we would require that facilities provide training biennially (every 2 years) after facilities conduct initial training for their emergency program. In addition, we propose to require additional training when the emergency plan is significantly updated.

i. Emergency Preparedness Requirements: Requirements for Testing

For inpatient providers, we propose to expand the types of acceptable testing exercises that may be conducted such that one of the two annually required testing exercises may be an exercise of their choice, which may include one community-based full-scale exercise, if available, an individual facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator. For outpatient providers, we propose to revise the requirement such that only one testing exercise is required annually, which may be either one community-based full-scale exercise, if available, or an individual facility-based functional exercise, every other year and in the opposite years, these providers may chose the testing exercise of their choice which may include a community-based full-scale exercise, if available, a facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator.

3. Proposals That Are Obsolete, Duplicative, or That Contain Unnecessary Requirements

a. Hospice Aide Training and Competency Requirements

We propose to revise § 418.76(a)(1)(iv) to remove the requirement that a State licensure program meet the specific training and competency requirements set forth in § 418.76(b) and (c) in order for such licensure to qualify a hospice aide to work at a Medicare-participating hospice. We would defer to State licensure requirements regardless of their content or format, and would allow states to set forth training and competency requirements that meet the needs of their populations. We believe that this change would streamline the hiring process for most hospices.

b. Medical Staff: Autopsies

We propose to remove the requirement for hospitals at § 482.22(d), which states that a hospital's medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. We propose to instead defer to State law regarding such medical-legal requirements.

c. Hospital and CAH Swing-Bed Requirements

We propose to remove the cross reference to § 483.10(f)(9) at § 482.58(b)(1) (for hospital swing-bed providers) and § 485.645(d)(1) (for CAH swing-bed providers). The cross-reference gives a resident the right to choose to, or refuse to, perform services for the facility if they so choose. If the resident works, the facility must document it in the resident's plan of care, noting whether the services are voluntary or paid, and, if paid, providing wages for the work being performed, at prevailing rates.

We propose to remove the cross-reference to § 483.24(c) at § 482.58(b)(4) (for hospital swing-bed providers) and § 485.645(d)(4) (for CAH swing-bed providers). This cross reference requires that the facility provide an ongoing activity program based on the resident's comprehensive assessment and care plan directed by a type of qualified professional specified in the regulation.

We propose to remove the cross-reference to § 483.70(p) at § 482.58(b)(5) (for hospital swing-bed providers) and § 485.645(d)(5) (for CAH swing-bed providers requiring facilities with more than 120 beds to employ a social worker on full-time basis).

We propose to remove the cross-reference to § 483.55(a)(1) at § 482.58(b)(8) (for hospital swing-bed providers) and § 485.645(d)(8) (for CAH swing-bed providers) requiring that the facility assist residents in obtaining routine and 24-hour emergency dental care.

d. Home Health Agency Home Health Aide Supervision Requirements

We propose to revise the requirement at § 418.76(h) related to completing a full competency evaluation when an aide is found to be deficient in one or more skills. Instead of completing a full competency evaluation, an aide would only be required to complete retraining and a competency evaluation directly related to the deficient skills.

e. CAH Disclosure Requirements

We propose to remove § 485.627(b)(1), the requirement for CAHs to disclose the names of people with a financial interest in the CAH. This is currently a requirement under the program integrity requirements at 42 CFR 420.206, which are referenced in the provider agreement rules in 42 CFR 489.53(a)(8). The provider agreement rules note that the basis for termination of the provider agreement includes failure of the provider to furnish ownership information as required in § 420.206, making this CAH CoP requirement duplicative of those regulations.

C. Summary of Costs and Benefits

1. Overall Impact

This proposed rule would create savings and reduce burden in many areas. Several of the proposed changes would create measurable monetary savings for providers and suppliers, while others would create less quantifiable savings of time and administrative burden. We estimate a total annual savings of $1,123 million using the midpoints of estimated ranges. We also estimate a one-time implementation cost of $64 million.

2. Section-by-Section Economic Impact Estimates

Table 1 summarizes the provisions for which we are able to provide specific estimates for savings or burden reductions (these estimates are uncertain and could be substantially higher or lower, as explained in the regulatory impact analysis section of this proposed rule):

TABLE 1—SUMMARY OF COSTS AND BENEFITS

Provider or supplier type and description of proposed provisions	Frequency	Number of affected entities	Estimated annual savings or benefits ($millions)
Religious Nonmedical Health Care Institution:			
• Discharge Planning	As patients are discharged (Estimated 619 annual discharges).	18	(*)
Ambulatory Surgical Center:			
• Governing Body and Management	Upon failed hospital transfer agreement attempts.	5,557	(*)
• Patient Admission, Assessment and Discharge (History and Physical) **.	Every patient admission to an ASC or hospital outpatient.	[1] 5,557 [2] 5,031	454
• Medical Records	Recurring annually	5,557	0
Hospices:			
• Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment.	Recurring annually	1,151	80
• Hospices That Provide Hospice Care to residents of a SNF/NF or ICF/IID.	Recurring annually	4,602	(*)
• Hospice Aide and Homemaker Services	Recurring annually	3,498	2
Hospitals:			
• Quality Assessment and Performance Improvement Program	Recurring annually	5,031	28
• Medical staff: Autopsies	Recurring annually	5,031	0
• Infection Control	Recurring annually	5,031	105
• Special requirements for hospital providers of long-term care services (“swing-beds”).	Recurring annually	5,031	30
• Special Requirements for Psychiatric Hospitals	Recurring annually	574	62
Transplant Programs:			
• Various provisions related to performance ***	Recurring annually	750	[3]
Home Health Agencies:			
• Patient rights	Recurring annually	12,624	55
• Home health aide services	Recurring annually	12,624	0
• Clinical records	Recurring annually	12,624	0
Critical Access Hospitals:			
• Provision of Services	Recurring biennially	1,343	2
• Organizational structure	Recurring annually	1,343	(*)
• Special requirements for hospital providers of long-term care services (“swing-beds”).	Recurring annually	1,246	86
Comprehensive Outpatient Rehabilitation Facilities:			
• Utilization Review Plan	Recurring annually	188	(*)
Community Mental Health Centers:			
• Assessment Update	Recurring annually	52	(*)
Portable X-Ray Services:			
• Qualifications of X-ray technicians ***	Annual	500	31
• Removing written orders	Annual	500	29
RHC (4,160 clinics) & FQHC (7,874 center locations):			
• Provision of Services	Recurring biennially	12,034	7
• Program Evaluation	Recurring biennially	12,034	9
Emergency Preparedness for Providers and Suppliers:			
• Annual Review of Emergency Preparedness Program	Recurring annually	72,844	94
• Emergency Plan	Recurring annually	68,254	7
• Training and Testing-Training Program	Recurring annually	69,196	33
• Training and Testing-Testing	Recurring annually	36,971	9
Total Annual Savings			1,123
Life-extending benefits for transplant patients **			[3]

* Amount is less than 1 million dollars.
** These include proposed changes to the following requirements: Special Requirements for Transplant Programs; Data submission, Clinical Experience, and Outcome Requirement for Re-approval of Transplant Programs; and Special Procedures for Approval and Re-Approval of Organ Transplant Programs.
*** This estimate is for first full year savings only and will increase in future years.
[1] (ACSs).
[2] (Hospitals).
[3] Not Quantified.

II. Provisions of the Proposed Regulations

A. Religious Nonmedical Health Care Institutions (RNHCIs)—Discharge Planning (§ 403.736(a) and (b))

Section 1861(ss)(1) of the Act defines the term ''Religious Nonmedical Health Care Institution'' (RNHCI) and lists the requirements that a RNHCI must meet to be eligible for Medicare participation. We have implemented these provisions in 42 CFR part 403, subpart G, ''Religious Nonmedical Health Care Institutions Benefits, Conditions of Participation, and Payment.'' Currently there are 18 Medicare-certified RNHCIs that are subject to the RNHCI regulations.

A RNHCI provides only non-medical items and services through non-medical nursing personnel on a 24-hour basis. These services are provided to beneficiaries who choose to rely solely upon a religious method of healing and for whom the acceptance of medical services would be inconsistent with their religious beliefs. ''Religious non-medical care'' or ''religious method of healing'' means care provided under established religious tenets that prohibit conventional or unconventional medical care for the treatment of the patient, and exclusive reliance on religious activity to fulfill a patient's total healthcare needs. The RNHCI does not furnish medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs or biologicals to its patients.

Section 403.736(a) and (b) of the RNHCI's CoPs, as amended in the November 28, 2003 **Federal Register** (68 FR 66710), requires RNHCIs to have a discharge planning process for patients. We reviewed the current CoPs and payment for RNHCIs at 42 CFR part 403, subpart G, in an effort to reduce burden and provide flexibility as feasible. As a result of the review, we identified discharge planning as one area where we could reduce burden. The current discharge planning requirements at § 403.736(a) and (b) require RNHCIs to have a discharge planning process that applies to all patients, and to assure that appropriate post-institution services are obtained for each patient, as necessary.

Currently, § 403.736(a)(1) requires RNHCIs to assess the need for a discharge plan for any patient identified as likely to suffer adverse consequences if there is no planning and for any other patient upon his or her request or at the request of his or her legal representative. In accordance with § 403.736, this discharge planning evaluation must be initiated at admission and must include the following:

- An assessment of the possibility of a patient needing post-RNHCI services and of the availability of those services.
- An assessment of the probability of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the RNHCI.
- The staff must complete the assessment on a timely basis so that arrangements for post-RNHCI care are made before discharge and so that unnecessary delays in discharge are avoided.
- The discharge planning evaluation must be included in the patient's care record for use in establishing an appropriate discharge plan. Staff must discuss the results of the discharge planning evaluation with the patient or a legal representative acting on his or her behalf.
- If the discharge planning evaluation indicates a need for a discharge plan, qualified and experienced personnel must develop or supervise the development of the plan.
- In the absence of a finding by the RNHCI that the beneficiary needs a discharge plan, the beneficiary or his or her legal representative may request a discharge plan. In this case, the RNHCI must develop a discharge plan for the beneficiary.
- The RNHCI must arrange for the initial implementation of the beneficiary's discharge plan.
- If there are factors that may affect continuing care needs or the appropriateness of the discharge plan, the RNHCI must reevaluate the beneficiary's discharge plan. The RNHCI must inform the beneficiary or legal representative about the beneficiary's post-RNHCI care requirements.
- The discharge plan must inform the beneficiary or his or her legal representative about the freedom to choose among providers of care when a variety of providers is available that are willing to respect the discharge preferences of the beneficiary or legal representative.

Since the RNHCI's religious tenets prohibit conventional or unconventional medical treatment of a beneficiary, we believe that the extensive requirements previously discussed are unnecessarily burdensome, because medical post-institution services are not utilized by RNHCI patients.

Based on our experience with RNHCIs, patients are routinely discharged to home and not to an acute or post-acute care medical provider or supplier. We do not see a need for RNHCIs to develop a discharge plan that includes medical care once a patient leaves the RNHCI, because doing so is not in keeping with the religious tenets and goals of the facility. However, we believe that it is important to discuss with the caregiver at home about a safe and healing environment at home and to monitor the individual to access any changes in the patient's well-being and the need to seek additional care. We would expect RNHCIs to have policies and procedures that address their discharge processes. If the RNHCI determines that a patient either does or does not require discharge instructions, this decision must be made based on the RNHCI's existing policies. Surveyors would be expected to review the RNHCI policies and confirm that either the existence or lack of discharge instructions is consistent with policies established by the RNHCI.

We propose a more condensed and flexible process for discharge planning and instructions for RNHCIs. Specifically, we propose to remove the requirements at § 403.736(a) and (b), proposing instead to require RNHCIs to provide discharge instructions to the patient and/or the patient's caregiver when the patient is discharged home. We also propose that paragraphs (c) and (d) be redesignated as paragraphs (b) and (c).

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction for future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on RNHCIs and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork'' Initiative, we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective.

We also note that such suggestions could include or expand upon comments submitted in response to the FY 2018 Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System RFI, found at *https://www.regulations.gov/docket?D=CMS-2017-0055.* Public comments on the RFI can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment

regulation docket on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: Mary Collins, (410) 786–3189.

B. Ambulatory Surgical Centers

Section 416.2 defines an ambulatory surgical center (ASC) as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, in which the expected duration of services would not exceed 24 hours following an admission. The surgical services performed at ASCs are scheduled, primarily elective, non-life-threatening procedures that can be safely performed in an ambulatory setting. Currently, there are 5,591 Medicare certified ASCs in the United States.

Section 1832(a)(2)(F)(i) of the Act specifies that ASCs must meet health, safety, and other requirements specified by the Secretary in regulation in order to participate in Medicare. The Secretary of the Department of Health and Human Services (the Secretary) is responsible for ensuring that the CfCs protect the health and safety of all individuals treated by ASCs, whether they are Medicare beneficiaries or other patients.

The ASC regulations were first published on August 5, 1982 (47 FR 34082) and have since been amended several times. On November 18, 2008, we published a final rule, entitled ''Medicare Program: Changes to the Ambulatory Surgical Center Conditions for Coverage'', (73 FR 68502) revising four existing health and safety CfCs and created three new health and safety CfCs. In addition, several other small changes have been made in the past several years to amend the emergency equipment requirements (77 FR 29002) and radiologic services requirements required in the ASCs (79 FR 27106).

1. Governing Body and Management (§ 416.41(b)(3)(i) and (ii))

Hospitalization Requirements

Section 416.41(b) outlines the patient hospitalization procedures that ASCs must have in place to participate in Medicare. Section 416.41(b)(1) states the ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care that surpass the capabilities of the ASC. Additionally, there are two requirements that also pertain to ASC patient hospital transfers. Section 416.41(b)(3)(i) and (ii) requires ASCs to have a written transfer agreement with a hospital that meets certain Medicare requirements or ensure all physicians performing surgery in the ASC have admitting privileges in a hospital that meets certain Medicare requirements. A written transfer agreement and physician admitting privileges is intended to make sure there is a relationship between the ASC and local hospital that would serve the patient in the event of a medical emergency. Over the past 5 years, we have heard from the largest ASC trade association and multiple ASCs that we need to address the widespread issue of the growing number of hospitals that are declining to work with ASCs (either by declining to sign a transfer agreement or by declining to allow admitting privileges to the hospital by physicians who work in ASCs) due to competition between hospital outpatient surgery departments and ASCs. CMS has continually worked with the ASCs and hospitals directly to resolve this requirement issue, however, several facilities have not been able to reach a positive outcome. Furthermore, we have seen no evidence of negative patient outcomes due to a lack of such transfer agreements and admitting privileges. Research reports published by the ASC Quality Collaborative indicate the national hospital transfer rate from an ASC to a hospital for care is about 1.25 per 1,000 ASC admissions (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ASC-Quality-Reporting/index.html*). ASCs are already required to have personnel trained and available for emergency response when there is a patient in the ASC. In addition, the ASC is expected to provide initial stabilizing treatment until the patient is transferred. Finally, the current requirement dates back to 1982, when ASCs were a newly emerging medical care option and there was reasonable concern as to needed emergency care being available.

EMTALA was enacted in 1986 and as its enforcement evolved over time this effectively has rendered such transfer agreements unnecessary, since EMTALA imposed requirements on all hospitals to provide emergency care without regard to prior arrangements until a patient could be stabilized and, as appropriate, either discharged because further care was not necessary, or transferred to another facility or care arrangement. Therefore, we conclude that these requirements are creating an administrative barrier to efficient ASC operations without any improvement in patient care or safety. In the absence of a transfer agreement or admitting privileges, ASCs would continue to have access to local emergency services to transfer patients to the nearest appropriate hospital for continued care. Hospitals are required to provide appropriate screening and stabilizing treatment for patients experiencing emergency medical conditions in accordance with the regulations set forth at § 489.24.

In light of these factors, we propose to remove the requirement for a written hospital transfer agreement or hospital physician admitting privileges at § 416.41(b)(3). We believe the proposed changes to the ASC hospitalization standard requirements would streamline ASC administrative operations and still assure the safety of these services while being less burdensome for Medicare-certified ASC facilities. The requirements in § 416.41(b)(1) and (2) continue to require the ASC to have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC and that the hospital must be a local hospital that meets the requirements for payment for emergency services under § 482.2. As part of this effective procedure, ASCs are not precluded from obtaining a hospital transfer agreements or hospital physician admitting privileges when possible. We would also like to solicit comments on burden that may result from the absence of a transfer agreement between ASCs and hospitals.

2. Patient Admission, Assessment and Discharge (§ 416.52(a)(1), (2), (3) and (4))

The current regulations at § 416.52 require ASCs to ensure that a physician or other qualified practitioner provide a comprehensive medical history and physical assessment completed not more than 30 days before the date of the scheduled surgery. We have received feedback from stakeholders that the current requirement is overly burdensome for a large majority of healthy patients, specifically those patients who are receiving minimally invasive surgical procedures that are performed under minimal sedation or local anesthesia alone. For example, cataract surgery is the most commonly performed ASC surgical procedure among Medicare beneficiaries. Modern cataract surgery is a short procedure using mild sedation and local anesthesia. Medical complications for cataract surgery before, during and after surgery are extremely rare. Other ophthalmic procedures, such as Yttrium-Aluminum Garnet (YAG) laser capsulotomy, does not require a local

anesthetic and is a painless 60 second procedure that can be completed during a routine patient visit. However, when it is performed in an ASC, which enables one laser to be utilized by multiple surgeons for procedures, the requirement for a history and physical is burdensome to the patient and medical staff without any additional benefits. One study published in the New England Journal of Medicine concluded that routine preoperative medical testing (blood counts, clotting studies, chemistry panels, electrocardiograms, chest x-ray, etc.) conferred no measurable value in reducing adverse medical events on the day of surgery or up to one week postoperatively (Schein OD, Katz J, Bass EB, et al. Study of Medical Testing for Cataract Surgery. The value of routine preoperative medical testing before cataract surgery. New England Journal of Medicine. 2000; 342(3): 168–75). Another article on this issue from the Cochrane Database of Systematic Reviews reviewed three randomized clinical trials and also found that routine preoperative testing did not increase the safety of cataract surgery (Keay L, Lindsley K, Tielsch J, Katz J, and Schein O. Routine preoperative medical testing for cataract surgery, 2012;3:CD007293). These results are consistently found for other ambulatory surgeries. For example, one study tested over one thousand patients over a wide range of surgeries and found no increase in adverse events as a result of no preoperative testing (Chung F, Yuan H, Yin L, Vairavanathan S, and Wong DT. Elimination of preoperative testing in ambulatory surgery. Anaesth Analg. 2009 Feb: 108(s):467–75). Another and much larger study reviewed the literature on a broad range of ambulatory surgeries and examined records of results for over 73,000 patients who underwent various hernia surgeries and found that preoperative testing was not associated with rates of postoperative complications.

The vast majority of outpatient surgeries are performed on an outpatient or ''ambulatory'' basis precisely because they involve extremely low risk of complications due either to preexisting conditions or to the risk of the surgical procedure itself. Most such procedures are among those that are also routinely performed in physician offices. We further note that the specification of any short time period for the acceptability of pre-surgical evaluations (in other words, within 30 days) is inherently arbitrary and burdensome for the ASC patient population. For example, in the case of a cataract patient who needs a procedure in both eyes, a 31-day delay between the two operations would trigger the need for another physical examination and, possibly, another set of laboratory tests. Likewise, if an unanticipated event such as a death in the family required delaying a procedure by more than the 30th day after the examination, a duplicative examination and any necessary tests would be required. Moreover, if the examination and tests had been performed timely, but the results not transmitted in time, the duplicative examination and tests would be required.

We propose to remove the current requirements at § 416.52(a) and replace them with requirements that defer to the facility's established policies for pre-surgical medical histories and physical examinations (including any associated testing) and the operating physician's clinical judgment, to ensure patients receive the appropriate pre-surgical assessments that are tailored for the patient and the type of surgery being performed. We propose to require each ASC to establish and implement a policy that identifies patients who require an H&P prior to surgery. We propose that the policy would include the time frame for the H&P to be completed prior to surgery. ASCs may choose to continue the 30 day policy that has existed in regulation since 2008, or may choose a different time frame based on available evidence and standards of practice. We propose that the policy would be required to consider the age of patients, their diagnoses, the type and number of surgeries that are scheduled to be performed at one time, all known comorbidities, and the planned level of anesthesia for the surgery to be performed. ASCs would not be limited to these factors, and would be permitted to include others to meet the needs of their patient populations. Furthermore, we propose that each ASC's policy would be required to follow nationally recognized standards of practice and guidelines, as well as applicable state and local health and safety laws.

Particular subgroups of patients may benefit from more extensive and complete medical history and physical assessments prior to surgery. Those subgroups, for example, might include patients who cannot lie supine, have chest pain or shortness of breath, have pacemakers, have had a recent heart attack, on dialysis, or take insulin (Schein OD, Pronovost PJ. A Preoperative Medical History and Physical Should Not Be a Requirement for All Cataract Patients. DOI: 10.1007/s11606–017–4043–9, March 20, 2017.)

We would retain the requirement that the physician performing the surgery or other qualified practitioner perform a pre-surgical assessment for each ASC patient, including documentation regarding any allergies to drugs and biologicals. We would also retain the requirement that any documentation related to the H&P that may have been performed would be placed in the patient's medical record prior to the surgical procedure.

Our proposed change would simply eliminate the requirement for a pre-operative H&P, while allowing patient-specific physician decisions and ASC-wide policy decisions to determine what examinations and tests are necessary for each patient. Such decisions could be informed by specialty societies, medical literature, past experience, or other factors. We believe the proposed changes will reduce burden and provide flexibility for patients while maintaining a balance of health and safety requirements for providers.

In reading the discussion that follows, it is important to understand that the requirement for making a patient assessment at the ASC, on the day of surgery and before surgery commences, remains unchanged. This assessment addresses any new surgical risks for the patient with procedure-specific or patient-specific questions (for example, has the patient had a fever in the last 24 hours or, for a patient with diabetes, have there been any recent changes to random blood glucose levels with at-home monitoring?). The questions focus on any recent changes or updates to the patient's condition since the last H&P that might adversely impact the outcome of the procedure for the patient. This assessment must occur before proceeding with the procedure. Furthermore, we are not proposing to eliminate or discourage comprehensive pre-surgical H&Ps where warranted. To replace the current arbitrary 30-day rule applying to all patients, regardless of procedure or risk, we propose that each facility make an independent determination as to which procedures and which patient profiles would dictate requiring a pre-operative history and examination, taken before (but not necessarily 30 days before and possibly many months before) the day of surgery.

We request comment on whether we should make exceptions, such as for particular patient conditions or surgical procedures, that should not be entitled to such broad discretion, and for any evidence that would support such exceptions. We would also be interested in knowing if particular examinations or tests should be normal for those

conditions or procedures, and whether such standards would need be imposed by regulation or could rely on physician and facility judgment and practices.

3. Medical Records (§ 416.47)

The current regulations at § 416.47 require ASCs to maintain complete, comprehensive, and accurate medical records to ensure adequate patient care. Section 416.47(b) sets out the form and content of the record, including specific items that must be included in the medical record. To conform to the proposed changes to the medical history and physical examination requirements at § 416.52(a), we propose to revise the requirement at § 416.47(b)(2) that states ''Significant medical history and results of physical examination'', by adding ''as applicable.'' This proposed revision would reflect the fact that, in accordance with our proposed changes to § 416.52(a), not all ASC patients may have a medical history and physical examination report that would be included in the medical record.

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on ASCs and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork'' Initiative, we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to the RFI that was included in the CY 2018 OPPS/ASC proposed rule. Public comments in response to this RFI can be found at the following link: *https://www.regulations.gov/docket?D=CMS-2017-0091.* Public comments on the RFI can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation docket on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: CAPT Jacqueline Leach, USPHS, 410–786–4282.

C. Hospice

1. Hospice Aide and Homemaker Services (§ 418.76)

Under the current hospice CoP requirements at § 418.76, all hospice aides are required to meet specific, federally-established, training and education requirements. The requirements are based on the training and education requirements for home health aides as set forth at section 1891(a)(3)(D) and 1861(m)(4) of the Act. Specifically, the current CoPs (§ 418.76(a)) require that a hospice aide must be a person who has completed one of the following: A training program and competency evaluation as specified in the regulations; a competency evaluation program that meets the requirements specified in the regulation; a nurse aide training and competency evaluation program in accordance with the requirements set forth in the long term care requirements; or a State licensure program that meets the requirements at § 418.76(b) (training) and (c) (competency evaluation). At § 418.76(b) and (c) of the hospice CoPs, we specifically detail the content and format of aide education, training, and of competency evaluations, including the number of classroom and practical training hours that must be completed, the skills that must be addressed, and the general method (exam or practical observation) used for assessing competency in those various skills.

We initially proposed and finalized these requirements in order to be consistent with the requirements that apply to home health aides (§ 484.80). Historically, a significant number of hospice agencies were HHA-based, meaning that the same entity provides both hospice and home health care services, often utilizing the same pool of staff to furnish both services. Using similar requirements for both hospices and home health agencies streamlines operations for hospices that are home health agency based. Due to the evolution of the hospice industry as a whole, the proportion of HHA-based hospices has significantly declined, reducing the streamlining benefits that occur by having the same requirements for aides in both hospice and home health settings.

As the streamlining benefits for the hospice industry as a whole have reduced, the burden/benefit ratio related to meeting the prescriptive home health aide qualification requirements, which are required to be set forth in regulation by section 1891(a) of the Act, has shifted. While section 1891(a) of the Act requires CMS to establish prescriptive requirements for aides who provide services on behalf of home health agencies, the Act does not establish similarly prescriptive requirements for aides who provide services on behalf of hospices. In addition to the hospice aide qualifications that are established in the hospice CoPs, hospice aides must also be licensed, certified, or registered by the State in which they are practicing (if available), in accordance with the requirements at § 418.116(a). A hospice industry association conducted an informal survey of all 50 states and found that 76 percent of those states currently have their own hospice aide qualifications for licensure, certification, or registration. Therefore, we assume that in 76 percent of states, hospice aides are required to meet two different qualification standards (one for state licensure, certification, or registration; and one for compliance with the Federal CoPs).

This regulatory approach has created unintentional burden during the hiring process for all of the non HHA-based hospices, as well as those HHA-based hospices that do not share staff with the home health agency portion of their organization. The unintentional burden is the result of hospices having to verify during the aide hiring process that the applicant meets both the state licensure, certification, or registration requirements, and also meets the specific training and competency requirements set forth in the CoPs. State requirements may change at any time and hospices may receive employment applications from aides that have been trained in another setting such as nurse aide training in the long term care environment or private duty aide training not subject to Federal regulations, so hospices are burdened with the need to review, in detail, each employment applicant's training and competency content and format each time they need to make a new hire. For example, State requirements may specify a different number of training hours to be completed, a different format for assessing competency in a specific skill, or even a different set of mandatory skills in accordance with State scope of practice requirements. We believe that this is an unnecessary and inefficient use of hospice staff time that does not serve to improve patient care and safety.

To address these concerns, we propose to revise § 418.76(a)(1)(iv) to remove the requirement that a State licensure program must meet the specific training and competency requirements set forth in § 418.76(b) and

(c) in order to be deemed an appropriate qualification for employment. This change would defer to State licensure requirements, except in states where no requirements exist, regardless of their content or format, and would allow states to set forth training and competency requirements that meet the needs of their populations. We do not believe that it is necessary for the Federal government to oversee the qualifications established by states because these states have already demonstrated their willingness and ability to regulate this area along with federally established requirements. This change would also streamline the hiring process for most hospices. We would continue to require that hospice aides may only perform those skills that are consistent with the training that the aide has received (§ 418.76(g)(2)(iv)), and would continue to require that, if an area of concern is verified by the hospice during an on-site aide supervision visit, then the hospice must conduct, and the hospice aide must complete, a competency evaluation in accordance with § 418.76(c) and (h)(1)(iii). We believe that these requirements will ensure that aides only perform duties for which they are trained and that they perform such duties in a safe and effective manner. Furthermore, we would continue to require that hospices must comprehensively assess patients on a regular schedule and on an as needed basis (§ 418.54(a), (b) and (d)), assure that each patient's plan of care is developed and continually updated to meet each patient's needs as identified in the assessment process (§ 418.56(b) through (d)), assure that the plan of care reflects patient and family goals (§ 418.56(b) and includes all services (including aide services) necessary to manage pain and symptoms (§ 418.56(c)), and ensure that hospice care and services are provided in accordance with the plan of care and are based on all assessments of the patient and family needs (§ 418.56(e)). Furthermore, hospices would continue to be required to provide hospice care that optimizes comfort and dignity, and is consistent with patient and family needs and goals (§ 418.100(a)). Finally, hospices would continue to be required to maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement program that involves all hospice services, including aide services, that focuses on indicators related to improved patient outcomes, and takes actions to demonstrate improvement in hospice performance (§ 418.58). While deferring to state requirements for hospice aide qualifications would likely introduce a new level of variability in the aide hiring process, we believe that the remaining hospice CoPs would continue to assure that hospice aide services meet the needs of patients and families, and are delivered in a safe and effective manner.

2. Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment (§ 418.106(a)(1) and (e)(2)(i))

The June 5, 2008 Hospice CoP final rule (73 FR 32088) required hospices to ensure that the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs (§ 418.106(a)(1)). This requirement was implemented as a direct result of public comments that were submitted in regards to the May 2005 Hospice CoP proposed rule (70 FR 30840). The May 2005 Hospice CoP proposed rule proposed to retain longstanding requirements for pharmacist involvement in the planning and delivery of drugs and biologicals for patients that receive care in the hospice inpatient setting. Commenters suggested that we broaden our proposal and apply it to patients receiving care in all settings. The commenters stated that, since drugs are prescribed to virtually all hospice patients, these patients should benefit from the expertise of a pharmacist and the additional level of drug oversight required by the regulatory standards. We agreed with the commenters that it would be beneficial to patients to broaden the scope of the pharmacy requirements. For this reason, we finalized a requirement at paragraph (a), ''Managing drugs and biologicals,'' to require that each hospice ensures that the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs. Hospices have the option of using a licensed pharmacist or an individual who has an extensive and up-to-date knowledge of drugs, to fulfill this role.

At the time when this requirement was finalized in 2008, we estimated that 1,600 hospices (56 percent of all hospices) were already contracting with pharmacy benefit management companies to provide drugs and pharmacist services to each of their patients at a single bundled service rate. These hospices were already realizing the benefits of specialized drug management expertise in the absence of Federal regulations. Since 2008, the use of pharmacy benefit management companies, including their built-in pharmacy experts, has continued to grow at a rapid pace. Although there have been no formal studies on the proliferation of pharmacy benefit management company use in hospice, conversations with industry experts lead us to estimate that, at minimum, 75 percent of existing hospices use such services. Experts estimate that the more likely number is between 90 and 95 percent of hospices due to various factors that hospices find to be desirable, such as predictable capitated medication fees and direct to the patient door medication delivery services. Since the use of pharmacology experts has become routine due to the proliferation of pharmacy benefit management companies that provide pharmacist services for each patient bundled with drug and biologics supply services, we believe that it is no longer necessary to include a regulatory requirement specifically related to the use of a pharmacology expert. As pharmacy benefit management services bundle drug and biologics supply services with expert advice, and since industry experts estimate that at least 75 percent and as many as 95 percent of hospices use pharmacy benefit management services for reasons primarily unrelated to this specific regulatory requirement, we conclude that the vast majority of hospices, and thus the vast majority of hospice patients, will continue to receive such advice and guidance in the absence of regulation. This proposed change would allow hospices to more seamlessly integrate the information provided by the drug management expert into routine interdisciplinary group meetings rather than having to use burdensome formulaic approaches that hospices currently implement in order to demonstrate compliance with the regulation.

In addition to changes in the pharmacy benefit management landscape, there have also been significant changes in the hospice and palliative care nursing and physician landscapes. Since publication of the 2008 Hospice CoP final rule (73 FR 32088), the number of hospice and palliative care nursing and physician specialty training and certification programs has rapidly expanded. As more hospice and palliative care

nursing and physician specialists have entered the job market, more hospices are employing these clinicians with advanced skill sets. In hospices that do not use a pharmacy benefit management service, these clinicians typically fill the role of the required individual with education and training in drug management in addition to being the regular physician or nurse member of the interdisciplinary group. As these clinicians are already members of the core interdisciplinary group in accordance with the requirements at § 418.56(a), we believe that hospices will continue to benefit from their expertise in the absence of Federal regulations. For these reasons, we conclude that the requirements at § 418.106(a)(1) are no longer necessary to assure patient safety and the effectiveness of hospice care. Furthermore, we believe that hospices may achieve a cost savings upon removal of this requirement because they will no longer need to assure a dedicated time in each interdisciplinary group meeting in order to be able to document that a specific conversation occurred among group members, and thus document compliance with the regulation. Therefore, we propose to delete the requirements at § 418.106(a)(1).

Hospices would continue to be required to comprehensively assess patients on a regular schedule and on an as needed basis (§ 418.54(a), (b) and (d)), and to assure that each patient's plan of care is developed and continually updated to meet each patient's needs as identified in the assessment process (§ 418.56(b) through (d)). To the extent that a hospice needs additional expert information or expertise beyond what is provided by hospice employees and the pharmacy expertise of any pharmacy benefit manager that a hospice may choose to use in order to meet a given patient's assessment, care planning, and care delivery medication-related needs, we would continue to require that it secure such information and expertise. Meeting each patient's needs would continue to be the responsibility of all Medicare-participating hospices in accordance with the requirements of all other hospice CoPs.

The 2008 Hospice CoP final rule (73 FR 32088) also required hospices, at § 418.106(e)(2)), to: (1) Provide a copy of the hospice written policies and procedures on the management and disposal of controlled drugs to the patient or patient representative and family; (2) discuss the hospice policies and procedures for managing the safe use and disposal of controlled drugs with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe use and disposal of controlled drugs; and (3) document in the patient's clinical record that the written policies and procedures for managing controlled drugs was provided and discussed. We believe that the hospice, as well as the patient, family, and caregivers share the responsibility and accountability for maintaining controlled substances in the home. We believe that hospices must assume responsibility to educate the patient and family about the proper use and disposal of controlled drugs and biologicals that are maintained in the home environment. The drug policies and procedures also help the hospice explain its own role in controlled drug management.

We believe that this requirement continues to be relevant, particularly in relationship to implementing proper storage and security precautions that can prevent theft and other drug diversion in the home, and proper disposal when a drug is no longer needed to prevent inappropriate access and environmental damage. Therefore, we continue to expect that hospices would have such policies and procedures for their own internal use as part of routine business practice. However, hospice policies and procedures are typically written in ways that are not easily understood by the general public. Hospice clinicians spend more time than expected explaining technical terms and otherwise translating the policies and procedures into layperson's terms. We do not believe that this process of explaining complex documents in a manner that is meaningful to patients and families is beneficial to patients, families, caregivers, or hospices.

We propose to replace the requirement that hospices provide a physical paper copy of policies and procedures, which are written to guide the actions of hospice staff, with a requirement that hospices provide information regarding the use, storage, and disposal of controlled drugs to the patient or patient representative, and family, which can be developed in a manner that speaks to the perspectives and information needs of patients and families. This information would be provided in a more user-friendly manner, as decided by each hospice, which we believe can improve comprehension and maximize the effectiveness of the education effort. Furthermore, by providing information in a more user-friendly manner, hospices would be able to eliminate time spent explaining technical terms and other otherwise translating the policies and procedures into layperson's terms. This would create more efficiency while simultaneously improving hospice-patient communications. Hospices would be free to choose the content and format(s) that best suits their needs and the needs of their patient population. We propose to require that, regardless of the format chosen, this information must be provided to patients and families in a manner that allows for continual access to the information on an as-needed basis in order to assure that patients and families have information available when they need it. CMS is soliciting input concerning what a standardized educational format should entail, including whether the format should be paper or electronic; in writing, pictorial, video, or audio; what general subjects should be addressed in regards to storage, disposal, use, and risks; and what specific content should be included to minimize opioid diversion and maximize safety.

We would continue to require that hospices discuss the information regarding the safe use, storage and disposal of controlled drugs with the patient or representative, and the family, in a language and manner that they understand to ensure that these parties are effectively educated. This requirement is included in the current hospice CoPs and is consistent with Department of Health and Human Services guidance regarding Title VI of the Civil Rights Act (''Guidance to Federal Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons,'' 68 FR 47311, August 8, 2003, *https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-Federal-financial-assistance-recipients-title-VI/*). We continue to expect hospices to utilize technology, such as telephonic interpreting services and any other available resources for oral communication in the individual's primary or preferred language. We would also continue to require that hospices document in the patient's clinical record that the information was provided and discussed.

3. Hospices That Provide Hospice Care to Residents of a SNF/NF or ICF/IID (§ 418.112 (c)(10) and (f))

Section 418.112(f) of the hospice CoPs, as finalized in the 2008 Hospice CoP final rule (73 FR 32088), requires hospices to assure orientation of Skilled Nursing Facility/Nursing Facility (SNF/NF) or ICF/IID staff furnishing care to

hospice patients. This orientation is required to include information concerning the hospice philosophy, including hospice policies and procedures regarding methods of comfort, pain control, symptom management, as well as principles about death and dying, individual responses to death, patient rights, appropriate forms, and record keeping requirements. The intent of this standard is to ensure that facility staff who furnish care to residents who are hospice patients are provided information on the hospice philosophy and approach to care, much in the same way that home caregivers are routinely provided information on the hospice philosophy and approach to care. It is the hospice's responsibility to coordinate the trainings with representatives of the facility. It is also the hospice's responsibility to determine how frequently training needs to be offered in order to ensure that the staff furnishing care to hospice patients are oriented to the philosophy of hospice care.

We believe that the intent of the requirement to educate facility staff about hospice care continues to be an appropriate regulatory requirement. However, we believe that, as currently written and implemented, this requirement may create duplication when multiple hospices provide care to the residents of a single facility. Furthermore, by assigning sole responsibility for this effort to hospice providers, this requirement may impede joint hospice-facility collaboration and training innovations. Creating duplicative efforts and impeding collaboration may increase hospice burden without improving the care of hospice patients. Therefore, we believe that it is appropriate to revise the current requirement.

Specifically, we propose to remove § 418.112(f) and add a new requirement at § 418.112(c)(10), ''Written agreement,'' to address this issue. Moving the requirement for facility staff orientation to the standard related to the written agreement established between hospices and facilities would ensure that both entities negotiate the mechanism and schedule for assuring orientation of facility staff. Additionally, enabling hospices and facilities to negotiate their now shared role would encourage collaboration between both entities, avoid duplication of efforts with other hospices that are orienting the same facility staff, and provide incentives to facilities to become more engaged in the hospice orientation process for facility staff.

We are seeking public comment on all of the proposed hospice changes. In addition, we note that we seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on hospices and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork'' Initiative, we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to the RFI that was included in the FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements. Public comments in response to this RFI can be found at the following link: *https://www.regulations.gov/document?D=CMS-2017-0062-0001.* Public comments on the RFI can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation docket on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: Danielle Shearer, 410–786–6617.

D. Hospitals

1. Quality Assessment and Performance Improvement Program (§ 482.21)

On May 16, 2012, we published a final rule, entitled ''Reform of Hospital and Critical Access Hospital Conditions of Participation'' (77 FR 29034). In that rule, we finalized changes to the requirements of the ''Governing body'' CoP, § 482.12, and adopted a policy to allow one governing body to oversee multiple hospitals in a multi-hospital system. We noted in this rule that the regulations, as finalized, were intended to provide systems that own two or more hospitals with an option, but not a requirement, to use a system governing body for two or more hospitals. In those instances where a system believes that its interests are best served by using a system governing body legally responsible for two or more hospitals, under the CMS regulations, that system will have the flexibility to do so, just as system that owns two or more hospitals will have the flexibility to continue with the model of a separate governing body for each hospital in its system if it determines that course would best serve its interests.

After publication of the May 2012 final rule, we received a considerable amount of feedback regarding our responses in the rule (77 FR 29061) where we discussed our interpretation of the Medical staff CoP at § 482.22 as requiring that each hospital have its own independent medical staff despite the arguable ambiguity of the regulatory language. It was brought to our attention that, over the years, this apparently ambiguous language might have led some stakeholders to interpret § 482.22 as allowing for separately certified hospitals, as members of a multi-hospital system, to share a unified and integrated medical staff. This eventually led to us proposing a requirement in a February 7, 2013 proposed rule, entitled ''Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction—Part II'' (78 FR 9216), which proposed to prohibit the use of a unified and integrated medical staff subject to a system governing body.

In the May 12, 2014 final rule, Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction (79 FR 27105) that followed, and after carefully considering all of the arguments for and against allowing a system that owns two or more hospitals to use a unified and integrated medical staff structure for its member hospitals that are subject to a common system governing body, we came to the conclusion that it was in the best interest of hospitals, medical staff members, and patients for us to modify the proposed prohibition on the use of a unified and integrated medical staff for a multi-hospital system and its member hospitals so as to enable the medical staff of each hospital that is subject to a common system governing body to voluntarily integrate itself into a larger system medical staff.

The fact that many hospital systems had been using a unified medical staff model for a number of years, without evidence showing that such a model was detrimental to patients or decreased the quality of care delivered, was a major factor in our decision to allow hospitals and their respective medical staffs the flexibility to decide which medical staff framework worked best for

their particular situations. We received a large number of comments from individual physicians as well as national and State physician organizations that supported our proposed changes to reaffirm and make more explicit the requirement that each hospital to have its own medical staff, specifically those hospitals that are part of a multi-hospital system. These commenters stated they believe that allowing a multi-hospital system to have a unified and integrated medical staff instead of separate medical staffs for each hospital would destroy the concept of medical staff self-governance that is ''a basic requirement'' for TJC hospital accreditation and which is ''mandated by some states.'' Additionally, there were some comments from individuals as well as hospital leaders that stated that while they support the proposed requirement overall, they believe that there should be some allowance for hospitals within a system to share medical staff bylaws, rules, and regulations.

However, these arguments against allowing this flexibility through the CoPs did not provide any evidence that having a single and separate medical staff for each hospital within a system was inherently superior, particularly in the areas of patient safety and quality of care, to the unified and integrated medical staff model for two or more hospitals subject to a system governing body. We weighed this argument against the comments from the physician leaders and members of unified and integrated medical staffs who provided testimony and anecdotal evidence for the benefits of this type of structure. Additionally, we considered preliminary evidence that appeared to show that hospitals using a unified medical staff might be achieving some success in reducing Hospital-Acquired Conditions (HACs), Healthcare-Associated Infections (HAIs), and readmissions, and in improving patient safety and outcomes. During our preliminary development of this rule, we carefully considered any additional areas where we could provide further flexibility and reduce regulatory burden for hospitals. We were particularly interested in those areas that we had not considered or proposed in the previous rulemaking efforts discussed. As we noted with regard to the use of a unified medical staff model under a system governing body, much of the evidence and testimony provided to us at that time focused on observed improvements in patient safety, quality of care, and overall patient outcomes. In the May 2014 final rule previously referenced, one public commenter, writing on behalf of a multi-hospital system that the commenter references as the largest in their State, stated that ''we believe the concept of a single medical staff has substantially contributed to our success as an integrated delivery system and has accelerated our quality, safety and efficiency performance.'' The commenter also cited the system's achievements, which the commenter stated that they believe were a result of this single and integrated medical staff model: Core measures in the top quartile with excellent value-based purchasing scores according to CMS; lower in-hospital mortality rates that are statistically significant, that is, 17 percent lower than expected; lower hospital readmission rates that are statistically significant, that is, 15 percent lower than expected; and the second lowest congestive heart failure readmission rate in the nation, according to published CMS data.

Since those rules were published, we have not received any negative feedback on the regulatory changes or any evidence that the use of a unified medical staff model is detrimental to patients and their care. And because the potential benefits to using such a system appear to point to patient safety and quality of care specifically, we began to look at two areas in the CoPs for possible revision along these lines, two areas that we believe have the most direct impact on ensuring and promoting a culture of safety in hospitals—QAPI and infection control. We believe that applying the unified model to a hospital's QAPI program and/or a hospital's infection control program would be a natural progression for a multi-hospital system currently using a system governing body and a unified medical staff. By allowing a system governing body the option of unifying and integrating its various member hospital QAPI programs and/or infection control programs into unified programs incorporating each individual hospital's QAPI program and/or infection control program (and thus applying the greater resources of the system to each hospital's QAPI program and/or infection control program), we believe a system might be able to more efficiently and effectively disseminate innovations, solutions, and best practices for patient care to each of its member hospitals through these respective unified programs. The Health Research and Educational Trust, in partnership with the American Hospital Association in a March 2010 publication entitled, ''A Guide to Achieving High Performance in Multi-Hospital Health Systems,'' identified specific best practices associated with health systems (*http://www.hpoe.org/Reports-HPOE/highperformance3.2010.pdf*). The publication stated that ''due to the size and breadth of their organizations, multi-hospital health system leaders have significant impact on the quality of health care in the United States. More than half of all U.S. hospitals belong to multi-hospital health systems, and about 60 percent of all hospital admissions occurs in system hospitals. While a wide range of quality improvement mechanisms can be applied in individual hospitals, there has been a lack of actionable information that leaders of multi-hospital systems can leverage to improve quality across their systems.''

Therefore, we propose to apply this same level of flexibility and regulatory burden reduction to a hospital's QAPI program as an option for system governing bodies that directly control and are legally responsible for two or more separately certified hospitals. As with our allowances for system governing bodies and unified medical staffs noted previously, we believe that system governing bodies that are legally responsible for two or more separately certified hospitals should be given the flexibility to determine which model of a QAPI program works best for their individual member and separately certified hospitals. We also believe that, in addition to the efficiencies that might be gained in the management and administration of QAPI programs through the increased resources of the hospital system, there might also be significant improvements in patient safety and outcomes to be achieved through such resources. Allowing for a unified and integrated QAPI program for its member hospitals would provide a system governing body with the needed flexibility and ease of administration to more readily apply the best practices and innovations learned and developed at one hospital to other hospitals subject to the same system governing body that might be facing the same problem-prone areas of patient care. We believe that by allowing system governing bodies this regulatory option, greater communication between member hospitals would be fostered so that a culture of patient safety and quality care could then be more fully integrated throughout the system. Given this flexibility and opportunity for integration, we believe that member hospitals subject to the same system governing body would replace the approach of each hospital operating within its own ''silo,'' a still all-too-

common operating standard, even within multi-hospital systems, that thwarts advances and innovations in improving patient care across the system.

We propose a new standard at § 482.21(f), ''Unified and integrated QAPI program for multi-hospital systems''. We would allow that for a hospital that is part of a hospital system consisting of two or more separately certified hospitals subject to a system governing body legally responsible for the conduct of each hospital, the system governing body could elect to have a unified and integrated QAPI program for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system governing body would be responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital subject to the system governing body would have to demonstrate that: The unified and integrated QAPI program was established in a manner that took into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and the unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed. Our expectation is that the focus on quality assessment, performance improvement, and patient safety within a certified hospital that is part of a unified and integrated QAPI program would be maintained and enhanced through the benefits of such integration.

2. Medical Staff, Medical Records Services, and Surgical Services (§§ 482.22, 482.24, and 482.51)

Hospital Medical History and Physical Examination Requirements

The current CoP at § 482.22, ''Medical Staff,'' requires that a hospital have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the hospital. At § 482.22(c)(5), the hospital medical staff bylaws must include a requirement that a H&P be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The bylaws must also include a requirement that an updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the H&P are completed within 30 days before admission or registration. These medical staff bylaws requirements addressing patient H&Ps form the basis for similar requirements in the hospital CoPs at § 482.24, ''Medical Record Services,'' and § 482.51, ''Surgical Services.''

Current hospital H&P requirements were proposed and finalized between 2005 and 2007, and similar ASC requirements were finalized 1 year later. According to a February 28, 2017, Centers for Disease Control and Prevention (CDC) National Health Statistics Report (Hall MJ, Schwartzman A, Zhang J, Liu X. Ambulatory surgery data from hospitals and ambulatory surgery centers: United States, 2010. National health statistics reports; no. 102. Hyattsville, MD: National Center for Health Statistics. 2017), in 2010, 28.6 million ambulatory surgery visits to hospitals and ASCs occurred, with an estimated 48.3 million surgical and nonsurgical procedures performed. The report also states that an estimated 25.7 million (53 percent) ambulatory surgery procedures were performed in hospitals and 22.5 million (47 percent) were performed in ASCs during this time. Further, the report found that the most frequently performed procedures (for both ASCs and hospital outpatient/ambulatory surgery departments) included endoscopy of large intestine (4.0 million), endoscopy of small intestine (2.2 million), extraction of lens (2.9 million), insertion of prosthetic lens (2.6 million), and injection of agent into spinal canal (2.9 million). These statistics, which also show similarities between the characteristics of patients seen by ASCs and hospital outpatient/ambulatory surgery departments, combined with the evidence already discussed in section II.B.2, ''Patient Admission, Assessment and Discharge'' (§ 416.52(a)(1), (2), (3) and (4)) have led us to conclude that we should propose a less burdensome option for the assessment of a patient prior to a hospital outpatient/ambulatory surgery or procedure for specific patients and procedures.

Because the hospital H&P requirements apply to all hospital patients (not just ambulatory surgery patients, as in ASCs) and because these requirements are contained under three separate CoPs, any proposed hospital requirements for pre-surgical assessments in lieu of the current requirements for a comprehensive H&P would need to be structured somewhat differently than those proposed for ASCs. However, we are basing certain aspects of the proposed hospital requirements on those proposed for ASCs in order to take into account some of the similarities of the two provider types.

We would revise the current requirements at § 482.22(c)(5)(i) and (ii) with respect to medical staff bylaws to allow for an exception under the proposed paragraph (c)(5)(iii). We are retaining the current language in paragraphs (c)(5)(i) and (ii) that the H&P, and any update to it, must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy. We propose to include this same language regarding who can complete and document the assessment in the proposed provision at § 482.22(c)(5)(iii). This provision would require the medical staff bylaws to state that an assessment of the patient (in lieu of the requirements of paragraphs (c)(5)(i) and (ii)) be completed and documented after registration, but prior to surgery or a procedure requiring anesthesia services, when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at paragraph (c)(5)(v), specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services. The proposed paragraphs (c)(5)(iii) and (iv) would require the medical staff to develop and maintain a policy that identifies those patients for whom the assessment requirements of paragraph (c)(5)(iii) would apply. We are also proposing a new requirement at paragraph (c)(5)(v) for a medical staff that chooses to develop and maintain a policy for the identification of specific patients to whom the assessment requirements in paragraph (c)(5)(iii) would apply. Under this proposed paragraph, if the medical staff exercised the option to perform a simplified assessment in some cases, the written policy would have to indicate the specific outpatient surgical or procedural services to which it applied. The policy for each procedure would

need to indicate the hospital's consideration of patient age, diagnoses, the type and number of surgeries and procedures scheduled to be performed, comorbidities, and the level of anesthesia required for the surgery or procedure; nationally recognized guidelines and standards of practice for assessment of specific types of patients prior to specific outpatient surgeries and procedures; and applicable State and local health and safety laws.

In order to make clear that this proposed requirement would be an option that a hospital and its medical staff could elect to use at their discretion, we propose language that states ''the provisions of paragraphs (c)(5)(iii), (iv), and (v) do not apply to a medical staff that chooses to maintain a policy that adheres to the requirements of paragraphs (c)(5)(i) and (ii) for all patients.'' In other words, a hospital and its medical staff would be free to exercise their clinical judgment in determining whether a policy for identifying specific patients as not requiring a comprehensive H&P (or any update to it) prior to specific outpatient surgical or procedural services, and instead requiring only a pre-surgical assessment for these patients, would be their best course. Or, if a hospital and its medical staff decided against such a policy, then only the current H&P and update requirements (at §§ 482.22, 482.24, and 482.51) would continue to apply and the proposed requirements for this CoP, as well as those proposed for §§ 482.24 and 482.51, would not apply.

For the current CoP at § 482.24, ''Medical Record Services,'' we would revise the provisions at § 482.24(c)(4)(i)(A) and (B) regarding an H&P and its update to allow for an exception under proposed paragraph (c)(4)(i)(C) where are proposing to add a new requirement that, if applicable, the medical record would have to document assessment of the patient (in lieu of the requirements of paragraphs (c)(4)(i)(A) and (B) after registration, but prior to surgery or a procedure requiring anesthesia services, for specific outpatient surgical or procedural services.

The current CoP at § 482.51, ''Surgical Services,'' contains provisions at § 482.51(b)(1)(i) and (ii) that require, prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies that a medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration an updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration. We are revising these requirements to allow for an exception to them under proposed paragraph (b)(1)(iii), where we propose a new requirement that, prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies, an assessment of the patient must be completed and documented after registration (and in lieu of the requirements of paragraphs (b)(1)(i) and (ii)). This proposed requirement would only apply in those instances when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at § 482.22(c)(5)(v), specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services.

As we did in the ASC section's discussion of these proposed changes to the H&P requirements, we request comment on whether there are any evidence-based exceptions or specific guidelines, such as for particular patient conditions or surgical procedures, that would prohibit this level of discretion for determining those hospital outpatient surgery patients who would not require a comprehensive H&P prior to outpatient surgeries or procedures.

Contact: CDR Scott Cooper, USPHS, 410–786–9465.

3. Medical Staff: Autopsies (§ 482.22(d))

In the June 1986 final rule, Medicare and Medicaid Programs, Conditions of Participation for Hospitals (51 FR 22010), we finalized a regulation to recommend that a hospital's medical staff attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. Hospitals are further required to define a mechanism for documenting permission to perform an autopsy, and they must have a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed. In that final rule, we stated that autopsies were an essential educational tool which contributed to the quality of care furnished by a hospital. Medical-legal investigative autopsies are conducted by a coroner's or medical examiner's office to determine the circumstances under which someone died and combine a scientific inquiry into a death under a coroner's or medical examiner's legal jurisdiction (*https://www.cdc.gov/phlp/publications/topic/coroner.html*).

Although the regulations specify that hospitals should attempt to secure permission to perform autopsies in certain cases, each state has established specific standards, laws, and regulations regarding the performance of autopsies for medical-legal investigative purposes for hospital patients. According to CDC's Public Health Law Program, each State sets its own standards for what kinds of deaths require investigation and its own professional and continuing education requirements for individuals carrying out these investigations. For example, the Medicolegal Death Investigation system for the state of New York specifies the use of coroners and medical examiners, who have specific medical and residency qualifications. Maine's Medicolegal Death Investigation system only specifies the role of a medical examiner. Unlike the regulations of the individual States, § 482.22(d) does not provide specifics on who should perform an autopsy, nor does it delve into the specifics of the medical-legal investigation process. As with all other CoPs, our intention was not to be overly prescriptive or overly burdensome in our requirements. In this case, the individual States have more specific requirements than the CoPs.

After reexamining this CoP, and in an effort to reduce duplicative or redundant requirements for hospitals, we believe that it is appropriate to remove the requirement at § 482.22(d). We believe that more detailed, specific requirements regarding medical-legal investigations and autopsies for hospitals are more appropriately and more effectively covered by the individual State laws in which the hospital is located. Therefore, we propose to remove the requirement at § 482.22(d). However, we continue to believe that the performance of autopsies further advances medical knowledge.

Contact: Alpha-Banu Wilson, 410–786–8687.

4. Infection Control (§ 482.42)

Similar to our proposal for a unified and integrated QAPI program for multi-hospital systems previously discussed, we believe that the same level of flexibility and regulatory burden reduction can be applied to a hospital's infection control program. We firmly believe that the same efficiency of administration, and improved patient outcomes, patient safety, and quality of care would be achieved in the infection control realm through a consistent system-wide approach as would be

allowed by this proposed rule. Our expectation is that the focus on infection control within a certified hospital that is part of a unified and integrated infection control program would be maintained and enhanced through the benefits of such integration, and that the trajectory toward continued reductions in infections would be continued.

Therefore, we propose a new standard at § 482.42(c), ''Unified and integrated infection control program for multi-hospital systems.'' Like the proposed requirements for a unified and integrated QAPI program, the proposed standard for infection control would allow that for a hospital that is part of a hospital system consisting of multiple separately certified hospitals subject to a system governing body legally responsible for the conduct of each hospital, such system governing body could elect to have a unified and integrated infection control program for all of its member hospitals after determining that such a decision was in accordance with all applicable State and local laws. The system governing body would be responsible and accountable for ensuring that each of its separately certified hospitals met all of the requirements of this section. Each separately certified hospital subject to the system governing body would have to demonstrate that the unified and integrated infection control program: (1) Was established in a manner that took into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; (2) established and implemented policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration; (3) had mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed; and (4) designated a qualified individual(s) at the hospital with expertise in infection prevention and control to be responsible for communicating with the unified infection control program, for implementing and maintaining the policies and procedures governing infection control, and for providing infection prevention education and training to hospital staff.

We are specifically seeking comment on whether there are any other programs currently required under the CoPs for each separately certified hospital, beyond the QAPI and Infection control programs proposed here, that stakeholders believe would likewise be better managed under a system governing body legally responsible for the conduct of each separately certified hospital.

Contact: CDR Scott Cooper, USPHS, 410–786–9465.

5. Special Requirements for Hospital Providers of Long-Term Care Services (''Swing-Beds'') (§ 482.58(b)(1), (4), (5), and (8), and Identical CAH Requirements: § 485.645(d)(1), (4), (5), (6), and (7))

Section 1883 of the Act permits certain small, rural hospitals to enter into a swing-bed agreement, under which a hospital or CAH can use its beds as needed, to provide either acute or SNF care. Swing-beds are beneficial when a patient is ready to leave the acute care level of a hospital stay, but still requires further skilled nursing care. They are often the only option in rural areas to provide this level of care. As defined in our regulations, a swing-bed hospital is a hospital or CAH participating in Medicare that has CMS approval to provide post-hospital SNF care and meets certain requirements. Hospitals providing swing-bed services must meet all of the requirements at 42 CFR part 482, which includes the swing-bed requirements at § 482.58 for patients receiving swing-bed services, and CAHs providing swing-bed services must meet all of the requirements at 42 CFR part 485, subpart F, which includes the swing-bed requirements at § 485.645 for patients receiving swing-bed services.

The hospital CoPs at § 482.58(a)(1) and (2) specify that hospitals providing swing-bed services must be located in a rural area and have less than 100 beds. Section 482.58(a)(1) excludes from the count beds for newborns and beds in intensive care type inpatient units, and § 482.58(a)(2) requires that the hospital be located in rural area, which includes all areas not delineated as ''urbanized'' areas by the Census Bureau, based on the most recent census.

The CAH CoPs at § 485.645(a)(2) state that a CAH must not maintain more than 25 inpatient beds that may be used for the provision of inpatient or swing-bed services, and as required at § 485.635(b)(1)(ii), the CAH must furnish acute care inpatient services to patients who present to the CAH for treatment, so long as the CAH has an available inpatient bed and the treatment required to appropriately care for the patient is within the scope of services offered by the CAH (State Operations Manual, Appendix W).

Hospitals and CAHs must both meet eligibility requirements to be granted approval from CMS to provide swing-bed services. The swing-bed requirements within the hospital and CAH CoPs include a subset of cross-referenced long-term care requirements contained in 42 CFR part 483, subpart B, for which hospital and CAH swing-bed providers are surveyed as they are for all of the CoPs in their respective programs.

The long-term care requirements under 42 CFR part 483 frequently reference residents given the average length of stay in long-term care facilities (28 days for skilled nursing facilities and 835 days for nursing homes) (Medicare Skilled Nursing Facility (SNF) Transparency Data (CY2013), *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-03-09.html#*; Centers for Disease Control and Prevention, Nursing Home Care FastStats, *https://www.cdc.gov/nchs/data/series/sr_03/sr03_038.pdf*). However, individuals receiving swing-bed services in a hospital or CAH are receiving SNF services and generally have shorter length of stays, with an the average length of stay of 11.4 days (Centers for Medicare & Medicaid Services, Office of Enterprise Data and Analytics, 2016). Note that this is still less than the average 28-day length of stay in a SNF. While we understand that some patients receiving swing-bed services in a hospital or CAH may have longer than average length of stays, we have determined that some of the cross-referenced long-term care requirements for hospitals and CAH swing-bed providers are unnecessary and unduly burdensome given their focus on ''residents'' and longer length of stays. Thus, we propose to remove the following requirements:

- *§§ 482.58(b)(1) and (c) and 485.645(d)(1) (incorporating long-term care facility requirements at § 483.10(f)(9):* Under our current regulations at § 483.10(f)(9), the resident has a right to choose to or refuse to perform services for the facility, and the facility must not require a resident to perform services for the facility. Regulations at §§ 482.58(b)(1) and 485.645(d)(1) incorporate this resident right by reference. The resident may perform services for the facility, if he or she chooses.

The current requirement for LTCFs also states that residents of these providers who are receiving swing-bed services who choose to perform services for the facility may do so when the facility has documented the need or desire for the resident to work in the plan of care; the plan specifies the nature of the services performed and whether the services are voluntary or paid; compensation for paid services is

at or above prevailing rates; and the resident agrees to the work arrangement described in the plan of care. Provided that those receiving hospital and CAH swing-bed services are not residents and spend a limited amount of time receiving swing-bed services, we have determined that this is an unduly burdensome requirement. Swing-bed services are transitional SNF-level services provided on a temporary basis. As a result, only a limited number of the SNF requirements are applicable to these patients. Therefore, we believe that it is unlikely that patients receiving hospital and CAH swing-bed services would be assigned a job and given an opportunity to provide services at the hospital or CAH due to their relatively short length of stay. With the proposed removal of this requirement, a hospital or CAH may permit patients receiving swing-bed services to provide services at the facility upon mutual agreement between the patient and the facility; thus, we believe that this requirement is unnecessary. We expect hospital and CAH swing-bed providers who do offer patients the option of providing services for the facility to have current policies and procedures that reflect this policy that includes protocol for establishing an agreement between the two parties. In addition, in the absence of these requirements, we believe patients' rights requirements for hospitals at § 482.13 and CAHs providing swing-bed services at § 485.645(d)(3) (which incorporates the long-term care requirements that patients be free from abuse, neglect and exploitation) would address such situations. We would monitor for any unintended consequences, as well as through evaluation of complaints that might be submitted regarding involuntary work performed by patients receiving swing-bed services in hospitals and CAHs. We would also ensure patient protections were maintained via the survey process and the process used to determine allegations of non-compliance with Federal or State requirements.

- *§§ 482.58(b)(4) and 485.645(d)(4) (incorporating long-term care facility requirements at § 483.24(c)):* The facility must provide, based on the comprehensive assessment and care plan and the preferences of each resident, an ongoing program to support residents in their choice of activities and the activities program must be directed by a qualified professional who is a qualified therapeutic recreation specialist or an activities professional.

Similar to the requirements noted previously, we believe that this requirement is also unnecessary and burdensome for hospitals and CAHs, as patients receiving swing-bed services in a hospital or CAH are not long term residents of the facility and generally only receive swing-bed services for a brief period of time for transition after the provision of acute care services. We expect that for those patients who receive swing-bed services for an extended period of time, their nursing care plan—as required under § 482.23(b)(4) for hospitals and § 485.635(d)(4) for CAHs—is based on assessing the patient's nursing care needs and will support care that holistically meets the needs of the patient, taking into consideration physiological and psychosocial factors.

- *§§ 482.58(b)(5) and 485.645(d)(5) (incorporating long-term care facility requirements at § 483.70(p)):* Any facility with more than 120 beds must employ a qualified social worker on a full-time basis.

We propose to revise the requirements at §§ 482.58(b)(5) and 485.645(d)(5) for hospitals and CAHs. The requirement that hospital and CAH swing-bed providers with more than 120 beds employ a full-time social worker is not applicable to either provider type. In accordance with the hospital and CAH swing-bed requirements, hospital swing-bed providers are not permitted to have more than 100 beds while CAH swing-bed providers are not permitted to have more than 25 beds for the provision of inpatient or swing-bed services. Based on feedback from stakeholders, removing this requirement would eliminate confusion for providers and accreditation organizations.

- *§§ 482.58(b)(7) and 485.645(d)(7) (incorporating the long-term care facility requirement at § 483.55(a)(1)):* Under our long-term care facility requirements, the facility, must provide or obtain from an outside resource, in accordance with § 483.70(g), routine and emergency dental services to meet the needs of each resident. We believe that this requirement is unnecessary and unduly burdensome for hospital and CAH swing-bed providers, as patients receiving swing-bed services in a hospitals or CAHs are not ''generally long term residents'' of the facility and are meant to receive swing-bed services for a brief period of time for transition after the provision of acute care services. The American Dental Association recommends regular dental checkups at least once a year for routine dental care for adults over 60 years of age. With an average length of stay in a hospital or CAH swing-bed of 11.4 days and an average daily swing-bed census of 2 patients, we believe that it is unlikely that there is a need for routine dental services that cannot be provided on an outpatient basis. We expect that any required dental services that necessitate immediate treatment would be considered an emergency and would be addressed accordingly. In addition, the American Dental Association recommends that routine dental care be obtained at least every 6 months, which greatly exceeds that average length of stay in a hospital or CAH swing-bed. However, hospitals and CAHs are required to provide care in accordance with the needs of the patient that have been identified in such patients' plans of care; this could include non-emergency dental care. We expect that hospital swing-bed providers are currently addressing the emergent dental care needs of their patients under the existing hospital CoP at § 482.12(f)(2), which requires that hospitals have written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate. Similarly, we expect that CAH swing-bed providers are currently addressing the emergent dental care needs of their patients under the existing emergency services CoP at § 485.618, which requires CAHs to provide emergency care necessary to meet the needs of its inpatients and outpatients. As a result, we believe that this portion of the requirement is duplicative, given the current CoP requirements.

Contact: Kianna Banks, 410–786–3498.

6. Special Requirements for Psychiatric Hospitals (§ 482.61(d))

Section 482.61(d) of our regulations, as finalized in the June 1986 final rule (51 FR 22050), requires that progress notes be documented by the doctor of medicine (MD) or doctor of osteopathy (DO) responsible for the care of the patient and, when appropriate, others significantly involved in active treatment modalities. ''Others significantly involved in active treatment modalities'' has been interpreted as staff from other disciplines, such as rehabilitative therapy and psychology, which are significantly involved in active treatment modalities and interventions. The intent of this requirement is to assure that the patient's medical record contains documentation of the patient's response to treatment planning and course of treatment. This documentation also serves to apprise all staff about patient's progress and any new problems or regression. We believe that the intent of the requirement to record progress notes in the patient's medical record continues to be an appropriate regulatory requirement. However, we

believe that as currently written and implemented, this requirement requires clarification. We believe that non-physician practitioners, including physician assistants, nurse practitioners, psychologists, and clinical nurse specialists, when acting in accordance with State law, their scope of practice, and hospital policy, should have the authority to record progress notes of psychiatric patients for whom they are responsible. Therefore, we propose to allow the use of non-physician practitioners or MD/DOs to document progress notes of patient receiving services in psychiatric hospitals.

Contact: Kianna Banks, 410–786–3498.

We are seeking public comment on all of the proposed hospital changes. In addition, we note that we seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on hospitals and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork Initiative,'' we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to RFIs that were included in the following 2017 prospective payment regulations for hospitals:

- FY 2018 Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System found at *https://www.regulations.gov/docket?D=CMS-2017-0055.*
- CY 2018 Outpatient Prospective Payment System/Ambulatory Surgical Center proposed rule (*https://www.regulations.gov/docket?D=CMS-2017-0091*).
- FY 2018 Inpatient Rehabilitation Facility Prospective Payment System (*https://www.regulations.gov/document?D=CMS-2017-0059-0002*).
- FY 2018 Inpatient Psychiatric Facilities Prospective Payment System (*https://www.regulations.gov/document?D=CMS-2018-0053-0002*).

Public comments on the RFIs can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation dockets on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

E. Transplant Centers

Transplant programs, located within a transplant hospital that has a Medicare provider agreement, provide transplantation services for a particular organ type. Transplant programs must comply with the transplant center CoPs, located at §§ 482.72 through 482.104, and with the hospital CoPs. There are several types of transplant programs including heart, lung, liver, and kidney. Intestine, pancreas, and multi-organ transplants are performed within existing transplant programs. For the purposes of this discussion, we define a transplant center as a group of transplant programs that are located in a transplant hospital. A transplant program is a component of the transplant center, within a transplant hospital, that provides transplantation for a particular type of organ. Transplant programs are surveyed for compliance with the CoPs.

This proposed rule uses the term ''transplant center'' when discussing the current requirements and language used in the regulations. In accordance with our proposed nomenclature change, discussed later in this proposed rule, the term ''transplant program'' is widely used throughout the preamble and in the proposed regulation text.

Section 1881(b)(1) of the Act sets out our authority for the Secretary to prescribe regulations for facilities furnishing end stage renal disease care to beneficiaries, including renal transplant centers. Section 1861(e)(9) of the Act permits the Secretary to issue regulations for the health and safety of individuals furnished services in hospitals.

In response to the relative scarcity of donated organs compared to the number of people on transplant waitlists and the critical need to use these limited resources efficiently, we published a final rule that established CoPs for transplant centers on March 30, 2007, (Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants) which codified requirements for approval and re-approval of transplant centers. We also placed Medicare-approved transplant centers under the survey and certification enforcement process we use for all other providers and suppliers of Medicare items and services (72 FR 15198). The transplant center CoPs include data submission, clinical experience, outcome, and process requirements for approval and re-approval of transplant centers. The requirements focus on an organ transplant program's ability to perform successful transplants and deliver quality patient care, as evidenced by outcomes as well as sound policies and procedures. The CoPs include requirements to protect the health and safety of both transplant recipients and living donors.

We have continued to review and analyze the effectiveness of the transplant center CoPs, the effects of interpretive guidance, and the data derived from surveys of transplant programs. We also received comments from various stakeholders within the transplant center community that detailed the impacts of the implementation of the CoPs on transplant programs and transplant recipients. Upon further review, and taking into account input from various stakeholders, we believe that it is appropriate and necessary to revise the transplant center CoPs in order to reduce provider burden, increase long-term savings to the Medicare program, and eliminate obsolete or unnecessary requirements, while also continuing to protect the health and safety of transplant recipients and living donors.

Furthermore, we believe that revising the transplant center CoPs will positively impact organ donation and transplantation in the United States by increasing the number of transplants performed each year and increasing the organ utilization rate, for reasons we discuss in further detail below. According to the Organ Procurement and Transplantation Network (OPTN) 33,610, organ transplants were performed and 15,948 donors (both living and deceased) provided organs in the United States in 2016. However, as of the writing of this proposed rule, 117,104 people still need a lifesaving organ transplant in 2017 (number represents total waiting list candidates, *https://optn.transplant.hrsa.gov/,* July 2017). While strides are being made to improve organ donation and increase the number of organ transplants in the United States, there continues to be a shortage of organs.

Therefore, we propose to revise the transplant center CoPs, as follows:

1. Special Requirement for Transplant Centers (§§ 482.68 and 482.70)

Section 482.68 generally describes the requirements that a transplant center must meet in order to participate in the Medicare program; section § 482.70 sets out definitions of terms used in the regulations. Specifically, in addition to meeting all the CoPs as a hospital, a transplant center must meet the CoPs specified in §§ 482.72 through 482.104 in order to be granted approval from CMS to provide transplant services. Throughout the regulation, we use terminology relevant to transplantation and organ procurement to describe transplant centers, programs, living donors, and transplant center recipients. Because the terminology currently used in the regulation is not consistent with current nomenclature used throughout the transplant community and by the OPTN, Scientific Registry of Transplant Recipients (SRTR), and the Department of Health and Human Services (HHS), we propose to update the terminology within the hospital regulation at part 482 and the transplant regulations at §§ 482.68, 482.70, 482.72 through 482.104, and at § 488.61, for clarification and consistency. Specifically, we propose a nomenclature change which would:

- Replace the term transplant ''center'' in the regulation language with transplant ''program'' (each organ type would be a transplant program). A transplant program is located within a transplant hospital that provides transplantation services for a particular type of organ. Since individual transplant programs are surveyed for compliance with the CoPs, using the term transplant program throughout the regulation better aligns with current surveyor practice and will reduce provider confusion. In order to provide further clarity, we are also proposing to update the definitions at § 482.70.
- Consistently use Independent Living Donor Advocate (ILDA) throughout the regulation.
- Change ''beneficiaries'' to ''recipients''.

Since these changes would make our terms consistent with the terminology utilized by the OPTN and the transplant community, we believe these proposed changes would reduce provider confusion.

2. Data Submission, Clinical Experience, and Outcome Requirements for Re-Approval of Transplant Centers (§ 482.82)

Section 482.82 requires that transplant centers that are applying for Medicare re-approval meet all data submission, clinical experience, and outcome requirements in order to be re-approved. In the March 2007 final rule (72 FR 15198), we also finalized these requirements for initial Medicare approval of transplant centers, as described in § 482.80. Since the publication of the final rule, several studies have been published that examine the impact of these requirements on transplantation and organ utilization in the United States. A 2016 article published in the American Medical Association Journal of Ethics concluded that ''using measured outcomes for punitive purposes may have resulted in significant unintended consequences'' and that ''transplant professionals will, by necessity, adapt practice to minimize the risk of regulatory citation and loss of transplant volume'' which contributes to ''lower transplant rates (typically among higher-risk candidates)'' and increased organ discard of marginal organs. (Adler, Joel T. and Axelrod, David A. Regulations' Impact on Donor and Recipient Selection for Liver Transplantation: How Should Outcomes be Measured and MELD Exception Scores be Considered, AMA Journal of Ethics, Vol. Volume 18, Number 2: 133–142. Doi: 10.1001/journalofethics.2016.18.02. pfor1–1602, February 2016.).

Another study linked performance evaluations to transplant volume in kidney transplant centers. The authors observed that centers that had low performance evaluations were more likely to have fewer kidney transplants than other kidney transplant centers. The study stated that kidney transplant centers that were identified with poor outcomes ''may be more likely to have staff turnover which may lead to declines in transplant volume'' and ''[c]enters that have been evaluated with lower performance may generally become more conservative in overall acceptance rates of candidates and donor organs'' (Schold, JD, et al. The Association of Center Performance Evaluations and Kidney Transplant Volume in the United States. *American Journal of Transplantation 2013; 13: 67–75.* doi: 10.1111/j.1600–6143.2012.04345, 2013.).

Another study covering over 90,000 liver transplant candidates concluded that the transplant center regulations that were finalized in the March 2007 final rule (72 FR 15198) increased the likelihood that liver transplant candidates would be removed from the liver transplant candidate waitlist and that this policy change led to the sickest patients being increasingly ''denied this lifesaving procedure while transplant mortality risks remain unaffected.'' The study found that the 2007 regulations had the effect of altering waitlist management and clinical decision making, thereby increasing the removal of the sickest patients from the waitlist. The impacts were seen through a 16 percent increase in delisting of patients due to the severity of their illness after the implementation of the 2007 regulation, and likelihood of being delisted continued to increase thereafter. The authors concluded that the 2007 regulation, which aimed to improve patient outcomes, had the consequence of instead failing to show any benefit to liver transplant patients. The authors suggested that future national policy decisions consider rebalance of the waitlist and transplant outcomes scale (Dolgin, Natasha H. et al. Decade-Long Trends in Liver Transplant Waitlist Removal Due to Illness Severity: The Impact of Centers for Medicare and Medicaid Services Policy. Journal of the American College of Surgeons. Volume 222, Issue 6, Pages 1054–1065. DOI: *http://dx.doi.org/10.1016/j.jamcollsurg.2016.03.021,* June 2016.).

Another study of kidney transplantation found that most of the increases in the discard rate from 1988 to 2009 could be explained by recovery of organs from an increasing donor pool and changes in ''pumping'' or perfusion practices. ''However, the presence of an unexplained, residual increase suggests behavioral factors (*e.g.,* increased risk aversion) . . . may have played a role.'' (Darren E. Stewart, et al. Diagnosing the Decades-Long Rise in the Deceased Donor Kidney Discard Rate in the United States. Transplantation. 2017; 101: 575–587.).

A different approach was taken in a recent study using data from 2000 to 2015. This study found that by comparing donors from whom one only one kidney was discarded and the other was transplanted reasons for discard could be better assessed. In this study ''a large number of discarded kidneys were procured from donors whose contralateral kidneys were transplanted with good post-transplant outcomes.'' It found that when two kidneys were retrieved from a deceased donor, and one of the two was discarded and the other used in a transplant, it was often the case that these ''discarded organs could have possibly demonstrated excellent performance if transplanted'' and ''the use of even a fraction of them could substantially reduce the number of patients who never receive an organ.'' As for the cause of these discards, the authors analyzed several factors and stated that ''the current report card system for transplant centers in the

United States . . . creates a disincentive to broader organ acceptance for centers concerned about payment penalties'' and that ''realignment of [these] incentives to promote more appropriate utilization is a key factor in reducing discards.'' (Syed Ali Husain, et al. Characteristics and Performance of Unilateral Kidney Transplants from Deceased Donors. Clinical Journal American Society of Nephrology 13: 2018.)

We also received comments and feedback from pertinent stakeholders in the transplant community that align with the conclusions of these studies. For instance, UNOS has presented at public meetings that up to ⅓ of kidneys that are discarded could be successfully transplanted. Furthermore, the transplant community has noted that transplant programs may not use these kidneys due to the perception that they are of higher risk and that the utilization of these kidneys may lead to outcomes non-compliance under § 482.82. These programs have avoided using these kidneys for fear of non-compliance with the CoPs and potential Medicare termination of the program, despite evidence to the contrary that demonstrates that the use of these kidneys would not pose a problem for transplant recipients. The transplant community has therefore concluded that the regulations have led to behavioral changes in organ selection and transplantation on patients with fewer comorbidities and lower risk. This has resulted in transplant programs potentially avoiding performing transplant procedures on certain patients and many organs going unused.

While it was our intent to ensure quality of care in transplant programs with the implementation of the regulations in § 482.82, we acknowledge that the final regulation may have caused unintended consequences that impact transplantation and transplant programs in the U.S. Given the findings of published studies and articles, and the public feedback we have received, we believe that it is appropriate to remove these requirements for re-approval of transplant programs in the Medicare program.

Therefore, we propose to remove the requirements at § 482.82 that require transplant centers to submit data (including, but not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant beneficiary registration and follow-up, and living donor registration and follow-up), clinical experience, and outcome requirements for Medicare re-approval, and make conforming changes to § 482.102(a)(5) ''Condition of participation, Patient and living donor rights'' and § 488.61 ''Special Procedures for Approval and Re-Approval of Organ Transplant Centers.'' Although we propose to remove these requirements, we continue to strongly believe that transplant programs should focus on maintaining high standards that protect patient health and safety and produce positive outcomes for transplant recipients. Therefore, we will continue to monitor and assess outcomes, after initial Medicare approval, through the transplant and hospital QAPI programs. In addition, quality of care will be monitored by assessing the other transplant program CoPs, including §§ 482.72 through 482.104. We also encourage transplant programs and their respective hospitals' QAPI programs to conduct thorough analyses of adverse events, document such events, and implement improvement activities to prevent recurrences. We further note that transplant programs must continue to comply with the CoPs at §§ 482.72 through 482.104 and the data submission, clinical experience, and outcome requirements for initial Medicare approval under § 482.80. We believe this proposal will eliminate provider disincentives for performing transplantations and will lead to increased transplantation opportunities for patients on the waitlist; improved organ procurement for transplantation; greater organ utilization; lifesaving effects, reduced burden on transplant programs; and reductions in costs to both public and private insurance.

We are seeking public comment on the removal of this requirement.

3. Special Procedures for Approval and Re-Approval of Organ Transplant Centers (§ 488.61(f) Through (h))

Section 488.61 describes the survey, certification, and enforcement procedures for transplant centers, including the periodic review of compliance and approval as set out at § 488.20. Section 488.61(f) through (h) set out the process for our consideration of a transplant center's mitigating factors in initial approval and re-approval surveys, certifications, and enforcement actions for transplant centers. The provisions also set out definitions and rules for transplant systems improvement agreements. We propose to remove the requirements at § 488.61(f) through (h) for mitigating factors and transplant systems improvement agreements for the re-approval process for transplant centers. This change is complementary to the proposed removal of § 482.82, described previously. We believe that repeal of these paragraphs would significantly reduce transplant programs' regulatory burden by no longer requiring them to submit mitigating factors applications or enter into systems improvement agreements for outcomes non-compliance (for re-approval surveys, certifications, and enforcement actions for transplant programs). Transplant programs will continue to be afforded the opportunity to submit mitigating factors or to enter into transplant systems improvement agreements during the initial application process to the Medicare program under § 488.61 (f) through (h).

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on transplant programs and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork Initiative,'' we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to the RFI that was included in the FY 2018 Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System proposed rule. Public comments in response to this RFI can be found at the following link: *https://www.regulations.gov/docket?D=CMS-2017-0055.* Public comments on the RFI can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation docket on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: Alpha-Banu Wilson, 410–786–8687.

F. Home Health Agencies

Home health services are covered for the elderly and disabled under the

Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program, and are described in section 1861(m) of the Social Security Act (the Act). These services, provided under a plan of care established and periodically reviewed by a physician, must be furnished by, or under arrangement with, a home health agency (HHA) that participates in the Medicare or Medicaid programs. Services are provided on a visiting basis in the beneficiary's home, and may include the following:

- Part-time or intermittent skilled nursing care furnished by or under the supervision of a registered professional nurse.
- Physical therapy, speech-language pathology, and occupational therapy.
- Medical social services under the direction of a physician.
- Part-time or intermittent home health aide services.
- Medical supplies (other than drugs and biologicals) and durable medical equipment.
- Services of interns and residents if the HHA is owned by or affiliated with a hospital that has an approved medical residency training program.
- Services at hospitals, skilled nursing facilities, or rehabilitation centers when the services involve equipment too cumbersome to bring to the home.

Under the authority of sections 1861(o) and 1891 of the Act, the Secretary has established in regulations the requirements that an HHA must meet to participate in the Medicare program. These requirements are set forth in regulations at 42 CFR part 484, Home Health Services.

1. Patient Rights (§ 484.50(a)(3) and (c)(7))

Section 484.50(a)(3) of the January 2017 HHA CoP final rule (82 FR 4504), effective January 13, 2018, requires HHAs to provide verbal (meaning spoken) notice of the patient's rights and responsibilities in addition to the requirement to provide such notice in writing. Section 1891(a)(1)(E) of the Act requires additional oral notice of rights for specified information as follows:

- All items and services furnished by (or under arrangements with) the agency for which payment may be made under Medicare,
- The coverage available for such items and services under Medicare, Medicaid, and any other Federal program of which the agency is reasonably aware,
- Any charges for items and services not covered under Medicare and any charges the individual may have to pay with respect to items and services furnished by (or under arrangements with) the agency, and
- Any changes to the charges or items and services set forth in the previous bullets.

Section 1891(a)(1)(F) of the Act requires that HHAs provide the notice of patient rights in writing.

The requirements at § 484.50(a)(3) implement these statutory requirements, and require spoken notice of all patient rights, rather than limiting such notice to those rights specified in the Act. On July 28, 2017, we published a proposed rule entitled ''CY 2018 Home Health Prospective Payment System Rate Update; Home Health Value Based Purchasing Model; and Home Health Quality Reporting Requirements'' (82 FR 35270) that solicited public comments on ways to reduce regulatory burden. In response to this solicitation, we received feedback from HHA stakeholders that the requirement to provide verbal notice of all rights to patients and their representatives was overly burdensome to the HHA clinicians that would be required to discuss the notice with patients when they could be furnishing hands-on patient care during that time, and lacked evidence that such explanations would result in improvements to patient safety or care. Furthermore, comments received encouraged us to reexamine all burdens in the January 2017 HHA CoP final rule to weigh potential benefits against estimated costs.

We believe that the concerns expressed by commenters have merit. In light of this information, we believe that any benefits of this requirement are outweighed by the burdens imposed by this requirement. For this reason, we propose to delete the requirement that HHAs must provide verbal notification of all patient rights. This change would be consistent with the notice of patient rights requirements for other outpatient provider types, such as hospices, ambulatory surgery centers, and community mental health centers, for which written notice of patient rights is the only requirement. We propose to limit the verbal notification requirements to those requirements set out in section 1891(a)(1)(E) of the Act for which verbal notification is mandatory. We propose to revise § 484.50(c)(7) to implement this more limited verbal notification requirement. Revised § 484.50(c)(7) would require HHAs to verbally discuss HHA payment and patient financial liability information with each HHA patient as described above.

This change would not prevent states or Accrediting Organizations (AOs) from independently establishing and enforcing verbal notification requirements for all patient rights for purposes other than the HHA CoPs, nor would it prohibit HHAs from providing such verbal notification of all patient rights in the absence of Federal regulation. Furthermore, this change would not alter the other requirements at § 484.50(a), which requires HHAs to provide the notice of patient rights in writing, nor would it alter the requirements at § 484.50(f), Accessibility, which requires HHAs to provide information to patients in plain language and in a manner that is both accessible and timely to: (1) Persons with disabilities in accordance with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act, and (2) persons with limited English proficiency. While HHAs would no longer be required to provide a verbal notification of all patient rights, we would continue to expect that HHAs answer any questions from patients or their representatives regarding the content of the written notice of rights. We believe that this proposed change would continue to provide adequate notice to patients while reducing burden on HHAs.

2. Home Health Aide Services (§ 484.80(h)(3))

Section 484.80(h)(3) of the January 2017 HHA CoP final rule (82 FR 4504) requires that, when a supervisory visit identifies a deficiency in a home health aide's skills, the HHA must conduct, and the aide must complete, a full competency evaluation to assess all aide skills and identify any other skill deficiencies that were not identified while observing the aide performing care with a patient. In public comments submitted for the July 2017 proposed rule ''CY 2018 Home Health Prospective Payment System Rate Update'' (82 FR 35270), a commenter suggested that completing a full competency evaluation was overly burdensome for HHAs and aides. Although this comment was not submitted during the proposed rule public comment period for the HHA CoP proposed rule, we believe that the concern expressed by the commenter has merit. In light of this new comment, we reconsidered the requirement, and concluded that a full competency evaluation is unnecessary and overly burdensome when only certain skills have been identified as deficient. We propose to eliminate the requirement to conduct a full competency evaluation, and replace it with a requirement to retrain the aide regarding the identified deficient skill(s) and require the aide to complete a

competency evaluation related only to those skills. This targeted retraining and competency evaluation requirement would reduce the time spent completing competency evaluations and retraining efforts.

3. Clinical Records (§ 484.110(e))

In the January 2017 HHA CoPs final rule (82 FR 4504), effective January 13, 2018, we finalized a requirement, codified at § 484.110(e), that an HHA must make available, upon request, a copy of the patient's clinical record at the next home visit, or within 4 business days (whichever comes first). In response to the July 2017 proposed rule solicitation of public comment on burden reduction via the CY 2018 Home Health Prospective Payment System Rate Update (82 FR 35270), we received feedback from HHA stakeholders that this requirement was impractical for HHAs to comply with because providing the record at the next visit may not allow enough time for HHAs to create a physical or electronic copy of the clinical record content, provide that copy to the next visiting clinician who may not be scheduled to come into the HHA office prior to the visit due to the nature of home based care and the significant travel that HHA clinicians must do in order to make patient visits, and successfully deliver the copy to the patient. The comments suggested that the 4 business day timeline was more practical and is an appropriate regulatory requirement. We agree that providing the record at the next visit is not practical or even possible in some cases. Furthermore, we agree that retaining the 4 business day timeframe is an appropriate regulatory requirement. Therefore, we propose to remove the requirement that the requested clinical record copy must be provided at the next home visit.

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on HHAs and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork Initiative,'' we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective.

We also note that such suggestions could include or expand upon comments submitted in response to the RFI that was included in the CY 2018 Home Health Prospective Payment System Rate Update; Value-Based Purchasing Model; and Quality Reporting Requirements. Public comments in response to this RFI can be found at the following link: *https://www.regulations.gov/docket?D=CMS-2017-0100.* Public comments on the RFI can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation docket on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: Danielle Shearer, 410–786–6617.

G. Comprehensive Outpatient Rehabilitation Facilities (CORFs)—Utilization Review Plan (§ 485.66)

Section 485.51 of our rules defines a Comprehensive Outpatient Rehabilitation Facility (CORF) as a nonresidential facility that is established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons, at a single fixed location, by or under the supervision of a physician. As of May 2017, there were 188 Medicare-certified CORFs in the United States. Section 1861(cc)(2)(G) of the Act requires CORFs to maintain utilization review programs. Under this authority, the Secretary has established requirements at § 485.66 with respect to such programs. Currently, § 485.66 requires the CORF to have in effect a written utilization review plan that is implemented at least each quarter, to assess the necessity of services and promotes the most efficient use of services provided by the facility.

We propose to amend the utilization review plan requirements at § 485.66 to reduce the frequency of utilization reviews. We believe the requirement to implement a utilization review plan 4 times a year is overly burdensome and diverts staff from providing patient care. We propose to require the utilization review plan be implemented annually by the facility, which would allow an entire year to collect and analyze data to inform changes to the facility and the services provided. Changing the requirement from a quarterly to an annual review would not preclude the CORF from implementing their utilization review plan more frequently, if required by facility policy. We believe that an annual utilization review plan will serve as a useful measurement tool for the facility, and that the change from quarterly to annual would not negatively affect patient health and safety.

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on CORFs and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork'' Initiative, we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to RFIs that were included in the 2017 payment regulations. We refer readers to the public comments that were submitted in response to the RFI for the following 2017 payment regulations:

- End-Stage Renal Disease Prospective Payment System and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program found at *https://www.regulations.gov/docket?D=CMS-2017-0084.*
- CY 2018 Home Health Prospective Payment System Rate Update; Value-Based Purchasing Model; and Quality Reporting Requirements found at *https://www.regulations.gov/docket?D=CMS-2017-0100.*
- FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality found at *https://www.regulations.gov/document?D=CMS-2017-0062-0001.*
- FY 2018 Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System RFI, found at *https://www.regulations.gov/docket?D=CMS-2017-0055.*

• CY 2018 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates found at *https://www.regulations.gov/docket?D=CMS-2017-0091.*

• FY 2018 Inpatient Rehabilitation Facility Prospective Payment System found at *https://www.regulations.gov/document?D=CMS-2017-0059-0002.*

• FY 2018 Inpatient Psychiatric Facilities Prospective Payment System found at *https://www.regulations.gov/document?D=CMS-2018-0053-0002.*

• CY 2018 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B found at *https://www.regulations.gov/docket?D=CMS-2017-0092.*

• FY 2018 Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities found at *https://www.regulations.gov/document?D=CMS-2017-0060-0002.*

Public comments on the RFIs can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation dockets on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: CAPT Jacqueline Leach, USPHS, 410–786–4282.

H. Critical Access Hospitals

1. Organizational Structure (§ 485.627(b)(1))

Current regulations at § 485.627 require CAHs to disclose the names and addresses of its owners, those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with 42 CFR part 420, subpart C. Section 42 CFR part 420, subpart C, sets forth requirements for providers, Part B suppliers, intermediaries, and carriers to disclose ownership and control information and sets forth requirements for disclosure of information about a provider's or Part B supplier's owners and those with a controlling interest.

The disclosure of ownership provisions at 42 CFR part 420, subpart C, are also required under the provider agreement rules under 42 CFR part 489. The term ''provider agreement'' is defined in § 489.3 as an agreement between CMS and a provider or supplier to provide services to Medicare beneficiaries and to comply with the requirements of section 1866 of the Act (Agreements with Providers of Services; Enrollment Processes). Providers must meet the terms of the agreement to be qualified to participate in the Medicare program.

We propose to remove this disclosure requirement from the CAH CoPs as it is duplicative of requirements for the provider agreement. Specifically, disclosure of individuals with a financial interest in the CAH is a requirement under the provider agreement rules in § 489.12(a)(2) and must be completed during the provider enrollment process. This information must be disclosed on the provider's Medicare enrollment application (Form CMS–855A for CAHs) and the enrollment application must be updated with any changes, such as address changes, practice name or change of ownership of information and must be submitted to CMS. Also note that this is not a requirement in the hospital CoPs under 42 CFR part 482 because it is already a requirement in the provider agreement rules under § 498.12(a)(2).

Contact: Kianna Banks, 410–786–3498.

2. Provision of Services (§ 485.635(a)(4))

Current regulations at § 485.635 require CAHs to review policies and procedures annually. We believe that medical practice has evolved such that we can provide flexibility for facilities to review, correct, or change their policies and procedures. Based on our experience with medical care providers and information from organizations such as the Brookings Institution (*https://www.brookings.edu/testimonies/improving-health-care-quality-the-path-forward/*), the expanded use of Web-based information and resources has fundamentally changed patient care, medical practice, and education. It has enabled providers to easily adjust policies and procedures on an as-needed basis. We believe that a prescriptive requirement to review policies and procedures annually could be eliminated to allow providers to review biennially and update as necessary, or more frequently if needed. For example, we expect providers to update their policies and procedures as needed in response to regulatory changes, changes in the standard of care, or nationally recognized guidelines.

The current CoP at § 485.635(a)(4) requires a CAH to review its policies at least annually by the CAH's professional healthcare staff, including one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of § 485.631(a)(1). The policies that are reviewed must include the following:

• A description of the services the CAH furnishes, including those furnished through agreement or arrangement;

• Policies and procedures for emergency medical services;

• Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records;

• Rules for the storage, handling, dispensation, and administration of drugs and biologicals;

• Procedures for reporting adverse drug reactions and errors in the administration of drugs; and

• A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

• Procedures that ensure that the nutritional needs of post-hospital SNF inpatients are met in accordance with recognized dietary practices.

Based on feedback from stakeholders, the prescriptive annual schedule can be burdensome or, in some situations, ineffective. Providers stated that they make annual, monthly and biannual changes to their policies. Some have stated that they make changes as needed or infrequently. They also stated that the time that it took to review the policies varied. Some stated it would take as little as 2 hours while a few stated a much longer period time such as a month, depending on what was being changed. We believe that taking a month would represent a new facility or a facility that is experiencing major restructuring. After a careful review of the varied responses, we propose to provide flexibility and reduce burden by revising the requirement at § 485.635(a)(4) to, at a minimum, only require a biennial review of policies and procedures. The 2-year review would not preclude a facility from conducting a review more frequently if needed or organizing the review such that it would be completed over a 2-year period. Based on our experience with other providers, we believe that this approach would allow CAHs to maintain their health and safety policies in such a manner as to achieve the intended outcomes for all patients. Thus, we propose to change the requirement at § 485.635(a)(4) from ''annual'' to ''biennial''.

Contact: Mary Collins, 410–786–3189.

3. Special Requirements for CAH Providers of Long-Term Care Services (''Swing-Beds'') (§ 485.645(d)(1), (4), (5) and (8))

The special requirements for CAH swing-bed providers are nearly identical to the requirements for hospital providers of swing-bed services. As a result, please refer to the discussion on the special requirements for hospital providers of swing-bed services under section II.D.3 for the details of the proposed changes for these requirements. We propose the following revisions to the CAH swing-bed requirements:

- Revision of § 485.645(d)(1) to remove the cross-referenced long-term care requirement in § 483.10(f)(9), which requires that CAH swing-bed providers to offer residents the right to choose to or refuse to perform services for the facility and prohibits a facility from requiring a resident to perform services for the facility;
- Removal of § 485.645(d)(4), which requires CAH swing-bed providers to provide an ongoing activity program that is directed by a qualified therapeutic recreation specialist or an activities professional who meets certain requirements (cross-referenced long-term care requirement § 483.24(c));
- Redesignation of paragraphs (d)(5) through (9) as (d)(4) through (8), respectively;
- Revision of § 485.645(d)(4) (as redesignated) to remove the cross-referenced long-term care requirement § 483.70(p), which requires that CAH swing-bed providers with more than 120 beds to employ a qualified social worker on a full-time basis; and
- Revision of § 485.645(d)(7) (as redesignated) to remove the cross-referenced long-term care requirement § 483.55(a)(1), which requires CAH swing-bed providers to assist in obtaining routine and 24-hour emergency dental care to its residents.

Contact: Kianna Banks, 410–786–3498.

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on CAHs and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork'' Initiative'' we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to the FY 2018 Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System RFI, found at *https://www.regulations.gov/docket?D=CMS-2017-0055.* Public comments on the RFI can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation docket on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

I. Community Mental Health Center (§ 485.914(d))

On October 29, 2013, we published a final rule (78 FR 209) that established, for the first time, a set of requirements that Medicare-certified CMHCs must meet in order to participate in the Medicare program. These CoPs ensure the quality and safety of CMHC care for all clients served by the CMHC, regardless of payment source. These requirements focus on a person-centered, outcome-oriented process that promotes quality client care. These CoPs are set forth at 42 CFR part 485 and apply to all Medicare participating CMHCs.

Medicare certified CMHCs provide services to a wide range of clients, from those needing partial hospitalization program (PHP) services to clients needing routine counseling. Partial hospitalization services are an intense level of services needed ''to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization. . . .'' (section 1861(ff)(2) of the Act). As written, the current standard at § 485.914(d) requires the CMHC to update the client comprehensive assessment every 30 days regardless of the client's needs or treatment schedule. This 30 day update of the comprehensive assessment correlates with the CMS PHP payment regulations, requiring PHP clients to receive an updated active treatment plan every 30 days. Clients receiving PHP are more acute and typically receive care in the CMHC multiple days a week for several hours a day. The PHP client will have changing needs as they progress through their treatment plan; therefore, updating the assessment every 30 days or sooner if the client's condition changes continues to be an important requirement for the PHP client.

While the minimum 30 day update time fame at § 485.914(d) is needed for clients receiving PHP services, we do not believe that this time frame requirement supports the needs of all CMHC clients. Clients that do not receive PHP services may be seen weekly or every 2 weeks, while others are only seen every 2–6 months for a medication follow up. Requiring an updated assessment every 30 days may not be practical for the non-PHP client, causing either additional visits or phone calls from the CMHC to the client to document ''no changes in the client's assessment''. This is not an efficient use of CMHC clinician or client time. Therefore, we propose to modify this standard at § 485.914(d)(1) to require that the CMHC update each client's comprehensive assessment via the CMHC interdisciplinary treatment team, in consultation with the client's primary health care provider (if any), when changes in the client's status, responses to treatment, or goal achievement have occurred, and in accordance with current standards of practice. Additionally at § 485.914(d)(3), we propose to retain the minimum 30 day assessment update time frame for those clients who receive PHP services. We believe this proposed change will allow for the provider and client to choose a visit schedule that is appropriate for the client's condition and not cause extra work or time for documentation that is unnecessary. Ultimately, this proposed change may allow for greater flexibility for the provider and client, saving time for both.

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on CMHCs and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork Initiative,'' we are particularly interested in any suggestions to improve existing

requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to the RFI that was included in the CY 2018 OPPS/ASC proposed rule. Public comments in response to this RFI can be found at the following link: *https://www.regulations.gov/docket?D=CMS-2017-0091.* Public comments on the RFI can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation docket on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: CAPT Mary Rossi-Coajou, USPHS, 410–786–6051.

J. Portable X-Ray Services (§§ 486.104(a) and 486.106(a))

Portable x-rays are basic radiology studies (predominately chest and extremity x-rays) performed on patients in skilled nursing facilities, residents of long term care facilities and homebound patients. Under the authority of section 1861(s)(3) of the Act, the Secretary has established the CfCs that the supplier of portable x-ray services must meet to participate in Medicare and Medicaid, and these conditions are set forth at §§ 486.100 through 486.110. The portable x-ray CfCs set forth at § 486.104 were originally published on January 10, 1969 (34 FR 388) and were redesignated on September 30, 1977 (42 FR 528260), and amended on April 12, 1988 (53 FR 12015), August 30, 1995 (60 FR 45086), and November 19, 2008 (73 FR 69942). The portable x-ray CfCs set forth at § 486.106 were originally published on January 10, 1969 (34 FR 388) and were redesignated on September 30, 1977 (42 FR 52826) and further redesignated and amended January 9, 1995 (60 FR 2326), August 30, 1995 (60 FR 45086), and November 16, 2012 (77 FR 69372). The November 2012 revision to the portable x-ray requirements allowed nurse practitioners and non-physician providers acting within their scope of practice to order portable x-ray studies. The current regulations are inconsistent with other rules governing diagnostic studies, as described later in this section of this proposed rule. In order to improve consistency, we propose changes to both § 486.104, Condition for coverage: Qualifications, orientation and health of technical personnel and § 486.106, Condition for coverage: Referral for service and preservation of records.

At § 486.104, Condition for coverage: Qualifications, orientation and health of technical personnel, the portable x-ray technologist must meet any one of four training and education requirements in § 486.104(a)(1), (2), (3), or (4). The requirement focuses on the accreditation of the school rather than the competency of the individual. In contrast, § 482.26(c)(2), referring to qualifications of radiologic technologists in hospitals, is focused on the qualifications of the individual performing services as permitted by State law. Additionally, § 410.33(c), which sets forth the personnel requirements for non-physician personnel used by an independent testing facility to perform tests, requires that testing personnel, including x-ray technologists, must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State health or education department. These two other regulatory requirements that govern the same type of technologists do not have any accreditation requirements. Based on our survey findings in hospitals, which have not identified widespread patient safety or quality of care concerns related to the training and education levels of technologists, we do not believe that removing the school accreditation requirement from the portable x-ray personnel requirements would negatively impact portable x-ray patient health and safety.

We propose to remove the four training and education requirements for two reasons. First, paragraph (a)(1), and to some extent paragraph (a)(4), focus on the accreditation of the school where the technologist received training, instead of focusing on the qualifications of the technologist performing the diagnostic test. Radiologic technicians who practice in a hospital, and for whom there are no requirements to receive education and training by an accredited program, are legally allowed to perform any diagnostic imaging procedure, including computed topography scans, mammograms, sonograms, and many other procedures that are more complex and require more expertise than portable x-rays. In contrast, portable x-ray radiologic technicians typically perform basic x-rays of the limbs (hand, foot) and chest, and are limited in their duties by State scope of practice rules. For this reason we are aligning the current requirements at § 486.104(a)(1), (2), (3), and (4) with § 482.26(c)(2), which refers to qualifications of radiologic technologists in hospitals, and is focused on the qualifications of the individual performing services as permitted by State law. This change would not preclude state licensure entities and portable x-ray suppliers from establishing personnel requirements that are more stringent that the proposed Federal requirements.

Second, paragraphs (a)(2), (3), and (4) establish different personnel qualifications based on the date that a technologist received his or her education and training. We do not believe that it is efficient or necessary to have varying qualifications based simply on the date that such training was received. We propose to replace these four different qualifications with a single, streamlined qualification that focuses on the skills and abilities of the technologist. We believe that removing school accreditation requirements and simplifying the requirements will reduce regulatory burden, streamline the hiring process, and widen the pool of individuals who may be employed by portable x-ray suppliers to perform portable x-ray services, particularly those individuals who received training through the military for performing portable x-rays, as military training programs are not accredited.

Section 486.106(a)(2) contains specific requirements for the content of the order for portable x-ray services, and requires that physician or non-physician practitioners orders for portable x-ray services must be written and signed. The requirements at § 486.106(a)(2) are inconsistent with the order requirements at § 410.32, which also apply to portable x-ray suppliers, in two ways. First, the requirements at § 486.106(a)(2) have different order content requirements. Second, the requirements at § 486.106(a)(2) have the effect of limiting or precluding telephonic and electronic orders, which are often more efficient ordering methods. Section 410.32 allows for the diagnostic service to be ordered in writing, by telephone, or by secure electronic methods. Although, § 410.32 does not prescribe the form of an order. The Medicare Benefit Policy Manual (Pub. 100–02), chapter 15, section 80.6 provides additional guidance on § 410.32, and states:

''An order may be delivered via the following forms of communication:

- A written document signed by the treating physician/practitioner, which is hand delivered, mailed, or faxed to the testing facility; NOTE: No signature is required on orders for clinical diagnostic tests paid on the basis of the

clinical laboratory fee schedule, the physician fee schedule, or for physician pathology services;

- A telephone call by the treating physician/practitioner or his or her office to the testing facility; and
- An electronic mail by the treating physician/practitioner or his or her office to the testing facility.

If the order is communicated via telephone, both the treating physician/practitioner or his or her office, and the testing facility must document the telephone call in their respective copies of the beneficiary's medical records. While a physician order is not required to be signed, the physician must clearly document, in the medical record, his or her intent that the test be performed.

We propose to update § 486.106 (specific to portable x-ray services) to cross reference the requirements at § 410.32. We propose to retain the requirement that the portable x-ray order must include a statement on why it is necessary to perform a portable x-ray as opposed to performing the study in a facility where x-rays are more typically performed. This change would allow for portable x-ray services to be ordered in writing, by telephone, or by electronic methods. The change would also streamline the ordering process by avoiding the need to write two separate orders for the same study, one to meet the Medicare payment requirements in accordance with § 410.32 and its associated Manual guidance, and another to meet the content requirements of the regulation set forth at § 486.106. We believe the proposed change would allow for additional ordering flexibility to streamline ordering practices while maintaining ordering and documentation requirements consistent with all other diagnostic testing.

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on suppliers of portable x-ray services and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork Initiative,'' we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to the RFI that was included in the CY 2018 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B. Public comments in response to this RFI can be found at the following link: *https://www.regulations.gov/docket?D=CMS-2017-0092.* Public comments on the RFI can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation docket on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: Sonia Swancy, 410–786–8445.

K. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Provision of Services (§ 491.9(b)(4))

Currently, § 491.9(b)(4) requires RHCs and FQHCs to have their patient care policies reviewed at least annually by the designated group of professional personnel who advise the RHC or FQHC in developing these policies (described at § 491.9(b)(2)), and reviewed as necessary by the RHC or FQHC. We propose to reduce the frequency of policy reviews. We believe the requirement to review patient care policies annually is burdensome and diverts staff from providing patient care. We propose to require the patient care policies be reviewed on a biennial basis by the group of professional personnel. Changing the review requirement from annually to every other year would not preclude the RHC or FQHC from maintaining their current annual review, if they believe it is necessary or if it is required by facility policy. We believe that this approach would allow RHCs and FQHCs to maintain their health and safety policies in such a manner as to achieve the intended outcomes for all patients. Thus, we propose to change the requirement at § 491.9(b)(4) from ''annual'' to ''biennial''.

2. Program Evaluation (§ 491.11(a))

The current requirement at § 491.11(a) requires that the RHC or FQHC carries out, or arranges for, an annual evaluation of its total program. Some RHCs and FQHCs have reported to us that this requirement is burdensome and utilizes costly staff resources. We propose to revise the current requirement at § 491.11(a) by changing the frequency of the RHC or FQHC evaluation from annually to every other year. The revised requirement would then require a biennial evaluation of its total program. Changing the program evaluation requirement from annually to every other year would not preclude the RHC or FQHC from conducting an evaluation more frequently or maintaining their current annual evaluation, if they believe it is necessary or if it is required by facility policy. Furthermore, the proposed changes would give the RHC or FQHC the flexibility to focus only on certain program areas, if they choose to do so, for the off year in-between required program evaluations. The proposed change would reduce the paperwork burden of the RHC or FQHC and allow clinicians to focus more on patient care. We believe that an evaluation of the RHC or FQHC's total program every other year is sufficient to ensure consistent quality of care, and that the change from annual to biennial would not negatively affect patient health and safety. We welcome the public's comments on these proposed changes.

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on RHCs and FQHCs and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork'' Initiative, we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to RFIs that were included in the 2017 prospective payment regulations for most provider types. We refer readers to the public comments that were submitted in response to the RFI for the following 2017 payment regulations:

- End-Stage Renal Disease Prospective Payment System and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal

Disease Quality Incentive Program found at *https://www.regulations.gov/docket?D=CMS-2017-0084.*

- CY 2018 Home Health Prospective Payment System Rate Update; Value-Based Purchasing Model; and Quality Reporting Requirements found at *https://www.regulations.gov/docket?D=CMS-2017-0100.*
- FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality found at *https://www.regulations.gov/document?D=CMS-2017-0062-0001.*
- FY 2018 Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System RFI, found at *https://www.regulations.gov/docket?D=CMS-2017-0055.*
- CY 2018 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates found at *https://www.regulations.gov/docket?D=CMS-2017-0091.*
- FY 2018 Inpatient Rehabilitation Facility Prospective Payment System found at *https://www.regulations.gov/document?D=CMS-2017-0059-0002.*
- FY 2018 Inpatient Psychiatric Facilities Prospective Payment System found at *https://www.regulations.gov/document?D=CMS-2017-0105-0002.*
- CY 2018 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B found at *https://www.regulations.gov/docket?D=CMS-2017-0092.*
- FY 2018 Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities found at *https://www.regulations.gov/document?D=CMS-2017-0060-0002.*

Public comments on the RFIs can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation dockets on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: CAPT Jacqueline Leach, USPHS, 410–786–4282.

L. Emergency Preparedness for Providers and Suppliers

On September 16, 2016, we published a final rule entitled, ''Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers'' (81 FR 63860), which established national emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers (referred to collectively as ''facilities'' in the subsequent section) to plan adequately for both natural and man-made disasters and coordinate with Federal, State, tribal, regional, and local emergency preparedness systems. In that final rule, we emphasized the need for facilities to maintain access to healthcare services during emergencies, safeguard human resources, and maintain business continuity and protect physical resources. A facility's emergency preparedness program must include the following elements:

- Risk assessment and emergency planning
- Policies and procedures
- Communication plan
- Training and testing

After the publication of that final rule, we continued to review and analyze the final emergency preparedness requirements and pertinent stakeholder feedback. Upon further review, we believe that some emergency preparedness requirements could be modified or eliminated to reduce provider and supplier burden while continuing to maintain essential emergency preparedness requirements that preserve the health and safety of patients in the United States. The following proposals would simplify the emergency preparedness requirements, eliminate duplicative requirements, and/or reduce the frequency with which providers and suppliers would need to perform certain required activities. We note that the current emergency preparedness standards are similar amongst all provider and supplier types, with a few variations to account for differences in health care settings. For clarity in the discussion later in this section of this proposed rule, we often refer to the hospital regulatory citation and we include specific references to other provider or supplier types when necessary.

1. Annual Review of Emergency Preparedness Program (§§ 403.748, 416.54, 418.113, 441.184, 460.84, 482.15, 483.73, 483.475, 484.102, 485.68, 485.625, 485.727, 485.920, 486.360, 491.12, and 494.62 (a), (b), (c), and (d))

Facilities are currently required to annually review their emergency preparedness program, which includes a review of their emergency plan, policies and procedures, communication plan, and training and testing program. However, pertinent stakeholders continue to question whether an annual review of the emergency program is necessary or beneficial to the facility. In response to their comments, we are therefore proposing to change this requirement to require facilities to review their program at least every 2 years. This will increase the facility's flexibility to review their programs as they determine best fits their needs. We expect that facilities would routinely revise and update their policies and operational procedures to ensure that they are operating based on best practices. In addition, facilities should update their emergency preparedness program more frequently than every 2 years as needed (for example, if staff changes occur or lessons-learned are acquired from a real-life event or exercise).

As noted in the Emergency Preparedness final rule (81 FR 63860), ''. . . there are various infections and diseases, such as the Ebola outbreak in October, 2014, that required updates in facility assessments, policies and procedures and training of staff beyond the directly affected hospitals. The final rule requires that if a facility experiences an emergency, an analysis of the response and any revisions to the emergency plan will be made and gaps and areas for improvement should be addressed in their plans to improve the response to similar challenges for any future emergencies.''

The Assistant Secretary for Preparedness and Response (ASPR) Technical Resources, Assistance Center, and Information Exchange (TRACIE) located at: *https://asprtracie.hhs.gov/,* is an excellent resource for the various CMS providers and suppliers as they seek to implement the emergency preparedness requirements. TRACIE is designed to provide resources and technical assistance to healthcare system preparedness stakeholders in building a resilient healthcare system. There are numerous products and resources located within the TRACIE website that target specific provider types affected by the emergency preparedness aspects of this proposed rule. While TRACIE does not focus specifically on the requirements implemented in this proposed regulation, this is a valuable resource to aid a wide spectrum of partners with their health system emergency preparedness activities. We strongly encourage providers and suppliers to utilize TRACIE and leverage the information provided by ASPR.

2. Documentation of Cooperation Efforts (§§ 403.748(a)(4), 416.54(a)(4), 418.113(a)(4), 441.184(a)(4), 460.84(a)(4), 482.15(a)(4), 483.73(a)(4), 483.475(a)(4), 484.102(a)(4), 485.68(a)(4), 485.625(a)(4), 485.920(a)(4), 486.360(a)(4), 491.12(a)(4), and 494.62(a)(4))

Facilities are currently required to develop and maintain an emergency preparedness plan that includes a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the facilities' efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts. Upon further review of this requirement, we believe that elements of this requirement are unduly burdensome on facilities. Therefore, we propose to eliminate the requirement that facilities document efforts to contact local, tribal, regional, State, and Federal emergency preparedness officials and facilities' participation in collaborative and cooperative planning efforts. Facilities will still be required to include a process for cooperation and collaboration with local, tribal, regional, State and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation. We believe that eliminating this documentation requirement will reduce provider and supplier burden by not requiring facilities to demonstrate that they have contacted local, tribal, regional, State, and Federal emergency preparedness officials or participated in collaborative and cooperative planning in the community, while still requiring facilities to at least include a process for cooperation and collaboration. We continue to encourage facilities to participate, when available, in community cooperative and collaborative planning efforts and execute the training and testing requirements in § 482.15 (d) for hospitals and similar parallel citations for other facilities.

3. Annual Emergency Preparedness Training Program (§§ 403.748(d)(1)(ii), 416.54(d)(1)(ii), 418.113(d)(1)(ii), 441.184(d)(1)(ii), 460.84(d)(1)(ii), 482.15(d)(1)(ii), 483.73(d)(1)(ii), 483.475(d)(1)(ii), 484.102(d)(1)(ii), 485.68(d)(1)(ii), 485.625(d)(1)(ii), 485.727(d)(1)(ii), 485.920(d)(1)(ii), 486.360(d)(1)(ii), 491.12(d)(1)(ii), and 494.62(d)(1)(ii)

Facilities are required to develop and maintain a training program that is based on the facility's emergency plan. This emergency preparedness training must be provided at least annually and a well-organized effective training program must include initial training in emergency preparedness policies and procedures. We revisited the public comments received on the Emergency Preparedness proposed rule (81 FR 63890 through 63891) and determined that requiring facilities to provide annual training may be unduly burdensome. We are therefore proposing to change this requirement to require that facilities provide training biennially or every 2 years, after facilities conduct initial training on their emergency program. In addition, we propose to require additional training when the emergency plan is significantly updated. For example, when a facility makes substantial changes to the procedures or protocols within the emergency plan, we would require additional training on the updated emergency plan. Other non-significant updates, such as revisions to the communication plan regarding contact information for staff, could be sent in company memorandum or provided to the facility's staff through other means. These proposed changes give facilities additional flexibility to determine what is appropriate for their facility's or staff's needs while maintaining adequate readiness.

4. Annual Emergency Preparedness Testing (§§ 403.748(d)(2), 416.54(d)(2), 418.113(d)(2), 441.184(d)(2), 460.84(d)(2), 482.15(d)(2), 483.73(d)(2), 483.475(d)(2), 484.102(d)(2), 485.68(d)(2), 485.625(d)(2), 485.727(d)(2), 485.920(d)(2), 486.360(d)(2), 491.12(d)(2), and 494.62(d)(2))

Facilities are currently required to conduct exercises to test the emergency plan at least annually. The facility must conduct two emergency preparedness testing exercises every year. Specifically, facilities must:

- Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the facility experiences an actual natural or-man made emergency that requires activation of the emergency plan (including their communication plan) and revision of the plan as needed), the facility is exempt from engaging in a community-based or individual, facility based full-scale exercise for 1 year following the onset of the actual event;
- Conduct an additional exercise that may include either a second full-scale exercise that is community-based or individual, facility-based or a tabletop exercise that includes a group discussion led by a facilitator.

Upon further analysis of this requirement, and taking into account stakeholder feedback, we have determined that there is also a need to clarify and revise some of the requirements included in the Emergency Preparedness final rule (81 FR 63860). We propose to clarify our intent with regard to the types of testing exercises, specifically full-scale exercises and functional exercises. As noted in the Emergency Preparedness proposed rule (78 FR 79101), a full-scale exercise is a multi-agency, multijurisdictional, multi-discipline exercise involving functional (for example, joint field office, emergency operation centers, etc.) and ''boots on the ground'' responses (for example, firefighters decontaminating mock victims). We expect facilities to engage in such comprehensive exercises with coordination across the public health system and local geographic area, if possible. Moreover, a functional exercise examines or validates the coordination, command, and control between various multiagency coordination centers (for example, emergency operation center, joint field office, etc.). A functional exercise does not involve any ''boots on the ground'' (that is, first responders or emergency officials responding to an incident in real time). The term ''functional exercise'' more accurately reflects our intentions for the testing requirement in the Emergency Preparedness final rule (81 FR 63860). We believe that there are opportunities to reduce the burden for inpatient and outpatient providers to meet the testing requirement.

For providers of inpatient services, we propose to expand the testing requirement options such that one of the two annually required testing exercises may be an exercise of their choice, which may include one community-based full-scale exercise (if available), an individual facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator. As indicated in the Emergency

Preparedness proposed rule, ''A workshop resembles a seminar, but is employed to build specific products, such as a draft plan or policy (for example, a Training and Exercise Plan Workshop is used to develop a Multiyear Training and Exercise Plan)'' (78 FR 79101). Providers of inpatient services include RNHCIs, inpatient hospice facilities, Psychiatric Residential Treatment Facilities (PRTFs), hospitals, long-term care facilities (LTCFs), ICFs/IIDs, and CAHs. We believe this will allow greater flexibility for inpatient providers to meet this requirement. We note that although RNHCIs provide inpatient services, we have determined that changing their existing requirements to make them consistent with this proposed provision will be unduly burdensome as they are currently required to conduct a paper-based, tabletop exercise at least annually.

For providers of outpatient services, we believe that conducting two testing exercises per year is overly burdensome as these providers do not provide the same level of acuity or inpatient services for their patients. Therefore, we propose to require that providers of outpatient services conduct only one testing exercise per year. Furthermore, we propose to require that these providers participate in either a community-based full-scale exercise (if available) or conduct an individual facility-based functional exercise every other year. In the opposite years, we propose to allow these providers to conduct the testing exercise of their choice, which may include either a community-based full-scale exercise (if available), an individual, facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator. Providers of outpatient services include ASCs, freestanding/home-based hospice, Program for the All-Inclusive Care for the Elderly (PACE), HHAs, CORFs, Organizations (which include Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services), CMHCs, Organ Procurement Organizations (OPOs), RHCs, FQHCs, and ESRD facilities. Due to the nature of services provided by OPOs we propose to require that they have the option of providing either a tabletop exercise or workshop every year.

Lastly, we propose to clarify the testing requirement exemption by noting that if a provider experiences an actual natural or man-made emergency that requires activation of their emergency plan, inpatient and outpatient providers will be exempt from their next required full-scale community-based exercise or individual, facility-based functional exercise following the onset of the actual event. A facility's communication plan is part of their emergency plan, as is coordination with other community emergency preparedness officials (for example, emergency management and public health), and we expect that these elements, along with the completion of a corrective action plan, are part of the activation of their emergency plan.

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on all Medicare and Medicaid participating providers and suppliers mentioned in this section and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork'' Initiative, we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to RFIs that were included in the following 2017 payment regulations:

- End-Stage Renal Disease Prospective Payment System and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program found at *https://www.regulations.gov/docket?D=CMS-2017-0084.*
- CY 2018 Home Health Prospective Payment System Rate Update; Value-Based Purchasing Model; and Quality Reporting Requirements found at *https://www.regulations.gov/docket?D=CMS-2017-0100.*
- FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality found at *https://www.regulations.gov/document?D=CMS-2017-0062-000.*
- FY 2018 Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System RFI, found at *https://www.regulations.gov/docket?D=CMS-2017-0055.*
- CY 2018 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates found at *https://www.regulations.gov/docket?D=CMS-2017-0091.*
- FY 2018 Inpatient Rehabilitation Facility Prospective Payment System found at *https://www.regulations.gov/document?D=CMS-2017-0059-0002.*
- FY 2018 Inpatient Psychiatric Facilities Prospective Payment System found at *https://www.regulations.gov/document?D=CMS-2017-0105-0002.*
- CY 2018 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B found at *https://www.regulations.gov/docket?D=CMS-2017-0092.*
- FY 2018 Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities found at *https://www.regulations.gov/document?D=CMS-2017-0060-0002.*

Public comments on the RFIs can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation dockets on *www.regulations.gov.* The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: Kianna Banks, 410–786–3498.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of the section 3506(c)(2)(A)-

required issues for the following information collection requirements (ICRs).

A. Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/2016/may/oes_nat.htm*). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead costs (calculated at 100 percent of salary), and the adjusted hourly wage.

NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hour)	Fringe benefit ($/hour)	Adjusted hourly wage ($/hour)
Healthcare Support Worker	31–9099	$18.13	$18.13	$36
Physicians and Surgeons	29–1060	101.04	101.04	202
Physicians and Surgeons, All Other	29–1069	98.83	98.83	198
Physicians, Psychiatrists	29–1066	94.26	94.26	189
Surgeons	29–1067	121.59	121.59	243
Registered Nurse (RN—Quality Improvement, Home Care Coordinator, HealthCare Trainer, Quality Assurance Nurse, QAPI Nurse Coordinator, Infection Control Nurse Coordinator, Psychiatric RN)	29–1141	34.70	34.70	69
Medical Secretary (Clerical, Administrative Assistant)	43–6013	16.85	16.85	34
Administrative Services Manager (Facility Director)	11–3011	47.56	47.56	96
Management Occupations (Director, Community Relations Manager, Administrator)	11–0000	56.74	56.74	114
Pharmacist	29–1051	57.82	57.82	115
Medical and Health Services Manager (Administrator, Transplant Program Senior Administrator/Hospital Administrator/Medical and Health Services Managers, Program Director, Risk Management Director. QAPI Director, Organ Procurement Coordinator, Nurse manager, Director of Nursing, Nursing care facilities/skilled nursing facilities)	11–9111	52.58	52.58	105
Managers, All Others(Administrator)	11–9199	53.92	53.92	108
*Activities Specialist (Recreational Therapists, Nursing Care Facilities/SNFs)	29–1125	19.92	19.92	40
Internists (Medical Director, General Physician	29–1063	97.04	97.04	194
Family and General Practitioner (Medical Director)	29–1062	96.54	96.54	194
Physical Therapist (Director of Rehab)	29–1123	41.93	41.93	84
Healthcare Social Worker (Social Worker)	21–1022	26.69	26.69	53
Mental Health and Substance Abuse Social Worker (Social Worker)	21–1023	23.02	23.02	46
Nurse Practitioner (Clinician, Nurse Practitioner Outpatient Care Center)	29–1171	50.30	50.30	101
Mental Health Counselor	21–1014	22.14	22.14	44
Physician Assistant	29–1071	49.08	49.08	98
Licensed Practical and Licensed Vocational Nurses (Director of Nursing)	29–2061	21.56	21.56	44
First Line Supervisors of Office and Administrative Support Workers (Office Manager)	43–1011	27.83	27.83	56
Office Clerks, General (Clerical staff)	43–9061	15.87	15.87	32
Secretaries and Administrative Assistants (Clerical staff)	43–6010	19.39	19.39	38
Chief Executive	11–1011	93.44	93.44	186

*Salary information used is for Nursing Care Facility/SNF industry. As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. ICRs Regarding RNHCI Discharge Planning (§ 403.736(a) and (b))

Section 403.736 will reduce the extensive requirements for an RNHCI to coordinate with other medical providers for post-RNHCI care. The discharge evaluation must include an assessment of a patient's capacity for self-care and information regarding the care once the patient leaves the facility. The nursing staff would need to prepare the patient and/or their caregiver for discharge. Most patients are discharged to home or to another facility that adheres to the same religious tenets. Although all patients must have a discharge planning evaluation, not all patients require a discharge plan. Based on recent claims data, there was a combined annual total of 619 beneficiaries that stayed in the 18 facilities.

We estimate that the time currently required to develop and document discharge plans and activities is 1,238 burden hours (2 hours for each of the 619 beneficiaries discharged) and that it would be reduced by half. Of the approximately 619 annual discharges, we estimate that a RNHCIs burden would be reduced to one hour for each discharged individual. A RNHCI would not need to develop a discharge plan that includes medical care once a patient leaves the RNHCI because doing so would not be in keeping with the religious tenets of the patients they serve. We estimate that the healthcare support worker responsible for a patients discharge plan is paid at mean wage of $36, including 100 percent for fringe and overhead costs. Based on our experience with RNHCIs, we estimate that it would take 1 hour to develop the proposed discharge instructions and discuss them with the patient and/or caregiver. We estimate a total of 619 annual discharges from RNHCIs at a savings of $36 per discharge for a total savings of $22,284 ($36 × 619 hours).

C. ICRs Regarding ASC Governing Body and Management (§ 416.41(b)(3)(i) and (ii))

We propose to eliminate the requirements at § 416.41(b)(3) that states the ASC must have a written transfer agreement with a hospital or ensure all physicians performing surgery in the ASC have admitting privileges at a local hospital that meets CMS hospitalization requirements. All ASCs easily meet this requirement and have established a relationship with their local hospital and obtained an agreement as usual and customary practice for running an ASC with the exception of approximately twenty ASCs that have difficult relationships with their local hospitals. The savings would not be significant, however, it does affect the 20 ASCs by removing the requirement. The current information collection request for the ASC rules (OMB control number 0938–1071) does not address any potential burden associated with this requirement. We believe that having and maintaining written agreements is standard practice. Therefore, removing this requirement would not alter the current information collection burden for ASCs.

D. ICR Regarding ASC Medical Records (§ 416.47(b)(2))

We propose to revise § 416.47(b)(2) by adding the phrase ''(as applicable)'' to the significant medical history and results of physical examination requirement of documents that must be included in the medical record in order to conform to the changes that we are proposing to the mandatory medical history and physical examination requirement. There are no collection of information requirements associated with this proposed change because maintaining a medical record for each patient is a usual and customary practice in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

E. ICRs Regarding ASC Patient Admission, Assessment and Discharge (§ 416.52(a)(1), (2), (3) and (4))

At § 416.52 we propose to replace the requirement that every patient have a comprehensive medical history and physical examination (H&P) within 30 days prior to surgery in an ASC with a requirement that allows the operating physician and ASC to determine which patients would require more extensive testing and assessment prior to surgery. The burden associated with this requirement would be the time and effort necessary to create new policies for when, and whether, to require some form of history and physical that would require pre-operative examination and testing, and on what time schedule. The current information collection request for the ASC rules (OMB control number 0938–1071) does not account for any information collection related burden associated with the comprehensive H&P requirement. We assume that creating these policies (which could leave such decisions to the surgeon's discretion in most or all cases) would require 10 hours of physician time, 10 hours of RN time, and 10 hours of clerical time, at the preceding hourly rates, for a total of 30 hours per facility. This would be a one-time cost of $3,440 per facility ([10 × $243] + [10 × $69] + [10 × $32]), and $19.1 million for all 5,557 facilities. Therefore, this proposed requirement would increase the information collection related burden by $19.1 million and 166,710 hours (30 hours × 5,557 facilities) on a one-time basis for all ASCs. The information collection request will be revised to account for the additional burden.

F. ICRs Regarding Hospice Aide and Homemaker Services (§ 418.76)

At § 418.76(a) we propose to defer to State training and competency requirements, where they exist, for hospice aides. The information collection request for the hospice requirements (OMB control number 0938–1067) is currently under review at OMB. It estimates that a hospice would spend 5 minutes per newly hired hospice aide to document verification that an aide meets the required training and competency requirements, for a total of 372 annual burden hours for all hospices at a cost of $11,540. This proposed change to the actual training and competency requirements would not alter the requirement to document the fact that a hospice aide meets one of the training and competency requirements set forth in the rule; therefore there would be no change to the existing collection of information estimates because the estimates relate to the unchanged documentation requirements rather than the actual training and competency requirements that would be revised by this proposed change.

G. ICRs Regarding Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment (§ 418.106(a) and (e)(2)(i))

At § 418.106(a) we propose to remove the requirement that a hospice ensure that the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs. The information collection request for the hospice requirements (OMB control number 0938–1067, currently under review at OMB) states that the burden associated with this requirement is the time necessary to document the results of this consultation in each patient's clinical record. In the information collection request we assumed that an average hospice would confer with a pharmacist, and that the pharmacist would document the results of his/her consultation. We estimated that it requires 5 minutes to document the initial review of a patient's drug and biologicals. Additionally, we estimated that it requires 5 minutes of the pharmacist's time to document a review of updates to the patient's drug profile. Based on a 17 day median length of service, we assumed that each patient would likely receive one update to their plans of care. At an average hourly rate of $115 for a pharmacist, we estimated that it would cost a hospice $19 per patient ($115 × [5 minutes for initial + 5 minutes for 1 update]) and an annual cost of $6,764 ($19 × 356 patients). The total annual burden hours for all hospices was estimated to be 264,588 hours (1,587,527 patients × .1666 hour per patient), and the total annual burden cost for all hospices was estimated to be $30,163,013 ($19 per patient × 1,587,527 patients). Therefore, removing the requirement that a hospice must ensure that the interdisciplinary group confers with an individual with education and training in drug management would result in a burden reduction of 264,588 hours and $30,163,013.

We assume that, upon implementation of the proposed change to allow hospices to provide information regarding the safe maintenance and disposal of controlled drugs in a more user-friendly manner, hospices would develop understandable instructions in layperson terms to replace the copy of the policies and procedures that is currently provided. While the instructions could be created in any number of formats, such as a slide show, video, podcast, or pictograph, for purposes of our analysis we assume that hospices would create written instructions. We estimate that a hospice would use 1 hour of administrator time to develop a new form at $105 per hour. For all 4,602 hospices, the total initial cost would be $483,210.

The information collection request will be revised and sent to OMB.

H. ICRs Regarding Hospices That Provide Hospice Care to Residents of a SNF/NF or ICF/IID (§ 418.112(c)(10) and (f))

At § 418.112(f) we propose to allow hospices and long term care facilities the additional flexibility to negotiate the format and schedule for orienting long term care facility staff regarding certain hospice-specific information. A hospice and SNF/NF or ICF/IID must have a written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospices and the SNF/NF or ICF/IID prior to the provision of hospice care services. The burden associated with this requirement is the time and effort necessary to develop, draft, sign, and maintain the written agreement. As stated in the hospice information collection request (OMB control number 0938–1067, currently under review at OMB), the use of this type of written agreement is a usual and customary business practice and the associated burden is exempt from the PRA under the implementing regulations at 5 CFR 1320.3(b)(2). However, updating the written agreement to address this new requirement would not constitute a usual and customary business practice; therefore, we believe that a one-time burden to update the written agreement would be imposed by this change. For purposes of this analysis only, we estimate that each hospice would use 8 hours of administrator time to revise the existing written agreement. At a cost of $105 per hour for an administrator to complete this task, we estimate that the onetime cost per hospice would be $840. For all hospices the onetime cost would be $3,865,680 (4,602 hospices × $840) for 36,816 hours (4,602 hospices × 8 hours). The information collection request will be revised to account for this one time increase in burden and sent to OMB.

I. ICRs Regarding Hospital Quality Assessment and Performance Improvement (QAPI) Program (§ 482.21)

We propose a new standard at § 482.21(f), ''Unified and integrated QAPI program for multi-hospital systems''. We would allow that for a hospital that is part of a hospital system consisting of two or more separately certified hospitals subject to a system governing body legally responsible for the conduct of each hospital, the system governing body could elect to have a unified and integrated QAPI program for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system governing body would be responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital subject to the system governing body would have to demonstrate that: the unified and integrated QAPI program was established in a manner that took into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and the unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.

As stated in the information collection request for the hospital requirements (OMB control number 0938–0328), which is in the process of being reinstated, we estimate that the burden associated with updating and, in some instances, writing new hospital policies directly related to patient care would be an average of eight (8) hours annually for each member of hospital staff involved in the specific patient care policies addressed.

Patient care policy development (and revision) by hospital medical staff is essential to patient health and safety because it provides the framework within which all patient care services are furnished. Thus, we have included the involvement of a physician at approximately $1,584 annually (8 burden hours × $198), a QAPI nurse coordinator at $552 annually (8 burden hours × $69), and a medical secretary at $272 annually (8 burden hours × $34).

We estimate the necessary policy changes needed to comply with the requirements proposed in this rule would cost $2,408 per year ($1,584 + $552 + $272) for each of the 424 hospital systems that would be eligible to do so and that would choose to exercise this option. Therefore, the total annual cost for all eligible hospital systems to meet these information collection requirements would be approximately $1 million.

J. ICRs Regarding Hospital Medical Staff, Medical Records Services, and Surgical Services (§§ 482.22, 482.24, and 482.51)

At § 416.52 we propose to replace the requirement that every patient have a comprehensive H&P within 30 days prior to surgery in an ASC with a requirement that allows the operating physician and ASC to determine which patients would require more extensive testing and assessment prior to surgery. As discussed in ''Provisions of the Proposed Regulations,'' section II.D.2 of this proposed rule, there is a similar regulatory requirement for hospital outpatient surgery. Based on the substantial similarity between these two service settings, we propose, through the revisions to §§ 482.22, 482.24, and 482.51 discussed in section II.D.2, to provide an exception to these requirements for outpatient surgery in hospitals.

As stated in the information collection request for the hospital requirements (OMB control number 0938–0328), which is in the process of being reinstated, we estimate that the burden associated with updating and, in some instances, writing new hospital policies directly related to patient care would be an average of eight (8) hours annually for each member of hospital staff involved in the specific patient care policies addressed.

Patient care policy development (and revision) by hospital medical staff is essential to patient health and safety because it provides the framework within which all patient care services are furnished. Thus, we have included the involvement of a physician at approximately $1,584 annually (8 burden hours × $198), a nurse coordinator at $552 annually (8 burden hours × $69), and a medical secretary at $272 annually (8 burden hours × $34).

We estimate that the necessary policy changes needed to comply with the requirements proposed in this rule would cost $2,408 per year ($1,584 + $552 + $272) for each of the 5,031 hospitals that might choose to exercise this option. Therefore, the total annual cost for all hospitals to meet these information collection requirements would be approximately $12.1 million.

K. ICRs Regarding Hospital Medical Staff: Autopsies (§ 482.22)(d))

We propose to remove the requirement at § 482.22(d), which recommends that a hospital's medical staff attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. Hospitals are further required to define a mechanism for documenting permission to perform an autopsy, and they must have a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed. Since more detailed, specific requirements regarding medical-legal investigations and autopsies for

hospitals are covered by the individual State laws in which the hospital is located, there are no collection of information requirements associated with this proposed change.

L. ICRs Regarding Hospital Infection Control (§ 482.42)

We propose a new standard at § 482.42(c), ''Unified and integrated infection control program for multi-hospital systems.'' Like the proposed requirements for a unified and integrated QAPI program, the proposed standard for infection control would allow that for a hospital that is part of a hospital system consisting of multiple separately certified hospitals subject to a system governing body legally responsible for the conduct of each hospital, such system governing body could elect to have a unified and integrated infection control program for all of its member hospitals after determining that such a decision was in accordance with all applicable State and local laws. The system governing body would be responsible and accountable for ensuring that each of its separately certified hospitals met all of the requirements of this section. Each separately certified hospital subject to the system governing body would have to demonstrate that the unified and integrated infection control program: (1) Was established in a manner that took into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; (2) established and implemented policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, were given due consideration; (3) had mechanisms in place to ensure that issues localized to particular hospitals were duly considered and addressed; and (4) has designated a qualified individual(s) with expertise in infection prevention and control at the hospital to be responsible for communicating with the unified infection control program, for implementing and maintaining the policies and procedures governing infection control, and for providing infection prevention education and training to hospital staff.

As stated in the information collection request for the hospital requirements (OMB control number 0938–0328), which is in the process of being reinstated, we estimate that the burden associated with updating and, in some instances, writing new hospital policies directly related to patient care would be an average of eight (8) hours annually for each member of hospital staff involved in the specific patient care policies addressed.

Patient care policy development (and revision) by hospital medical staff is essential to patient health and safety because it provides the framework within which all patient care services are furnished. Thus, we have included the involvement of a physician at approximately $1,584 annually (8 burden hours × $198), an infection control nurse coordinator at $552 annually (8 burden hours × $69), and a medical secretary at $272 annually (8 burden hours × $34).

We estimate the necessary policy changes needed to comply with the requirements proposed in this rule would cost $2,408 per year ($1,584 + $552 + $288) for each of the 424 hospital systems that would be eligible to do so and that would elect to exercise this option. Therefore, the total annual cost for all eligible hospital systems to meet these information collection requirements would be approximately $1 million.

M. ICRs Regarding Special Requirements for Hospital Providers of Long-Term Care Services (''Swing-Beds'') (§ 482.58(b)(1), (4), (5), and (8), and Identical CAH requirements: § 485.645(d)(1), (4), (5), and (8))

At §§ 482.58(b)(1) and 485.645(d)(1) (cross-referenced long-term care requirement at § 483.10(f)(9)) we propose to remove the requirement for hospital and CAH swing-bed providers to provide the right for patients to choose to or refuse to perform services for the facility and if they so choose; (a) document in the resident's plan of care, (b) noting whether the services are voluntary or paid and (c) provide wages for the work being performed given the location quality, and quantity of work requiring comparable skills. We believe this requirement is unduly burdensome as we do not expect patient's receiving hospital or CAH swing-bed services have an average length of stay long enough to be positively impacted by providing services to the facility. We assume that each of the hospital swing-bed providers (478 hospitals) and CAH swing-bed providers (1,246 CAHs) has an activities specialist employed at $40 per hour who would oversee the residents who have chosen to perform services for the facility, and document and update the plan of care accordingly. We believe that given the limited budget of most rural providers, services are being provided to the CAH on a voluntary basis and that these providers are not compensating patients for providing these services. The current regulatory burden for compliance with this requirement is approximately $29 million for all hospital and CAH swing-bed providers, or $16,821 per hospital or CAH swing-bed provider (1,724 hospital and CAH swing-bed providers × $40 an hour for an activities specialist × 8 hours per week × 52 weeks per year), which are the cost savings to the providers as a result of the removal of this requirement.

At § 482.58(b)(4) (and § 485.645(d)(4)) (cross-referenced long-term care requirement at § 483.24(c)), we propose to remove the requirement for hospital and CAH swing-bed providers to provide an ongoing activity program that is directed by a qualified therapeutic recreation specialist or an activities professional who meets certain requirements as listed at § 483.24(c)(2). We assume that each of the hospital swing-bed providers (478 hospitals) and CAH swing-bed providers (1,246 CAHs) has an activities specialist employed at least part time at $40 per hour. CAHs are required to provide activity services by either a qualified individual who meet the requirements of § 483.24(c)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy. For the purpose of this analysis, we assume that the cost of each would be the same due to the rural location of CAHs. The current regulatory burden for compliance with this requirement is based on the activities specialist organizing, overseeing, and scheduling the activity. The cost savings as a result of the removal of this requirement are approximately $72 million for all hospital and CAH swing-bed providers, or $41,800 per hospital or CAH swing-bed provider (1,724 hospital and CAH swing-bed providers × $40 an hour for an activities specialist × 1,040 hours per year) which are the cost savings to the providers. Our analysis assumes that the reduced staffing is largely for part-time work assignment (1,040 hours annually) at hospital and CAH swing-bed providers. It is likely that many of the actual persons holding these positions were full-time workers not devoted solely to recreational therapy, whose hours will simply be reassigned to other functions, with providers ultimately saving these full-time equivalent hours through ripple effects on an even wider range of staffing functions through turnover over time.

We propose to remove the requirement at §§ 482.58(b)(5) and 485.645(d)(5) (cross-referenced long-

term care requirement at § 483.70(p) for hospital and CAH swing-bed providers to employ a qualified social worker on a full-time basis if the facility has more than 120 beds. Given that this provision is not applicable to either provider type due to the regulatory requirements for each, it does not impose a burden upon hospitals and as such, its removal would not result in a savings of economic burden hours or dollars.

At §§ 482.58(b)(8) and 485.645(d)(8) (cross-referenced long-term care requirement at § 483.55(a)(1)) we propose to remove the requirement for hospital and CAH swing-bed providers to assist in obtaining routine and 24-hour emergency dental care to its residents.

Under the current CoPs, hospitals and CAHs are currently required to address the emergent dental care needs of their patients at § 482.12(f)(2) for hospitals, and at § 485.618 (emergency services) for CAHs. As a result, we have calculated the burden associated with the provision of routine dental care for hospital and swing-bed patients. The American Dental Association recommends annual dental checkups for routine dental care for adults over 60 years of age. With an average length of stay in a hospital or CAH swing-bed of 1–2 weeks and an average daily census of 2 patients, we assume that 1 patient receiving swing-bed services will require routine dental services per month. While a dentist and dental hygienist provide the dental services, Medicare is billed for the provision of these services. The costs to the provider are related to the nursing activities associated with the patient receiving the dental services. The current regulatory burden for compliance with this requirement is approximately $2.9 million for all hospital and CAH swing-bed providers, or $1,682 per hospital or CAH swing-bed provider (1,724 hospital and CAH swing-bed providers × $69 an hour for a RN × 24 hours per year), which are the cost savings to the providers as a result of the removal of this requirement. The information collection requests will be revised and sent to OMB for approval (OMB control number 0938–0328 for hospitals and 0938–1043 for CAHs).

N. ICRs Regarding Special Requirements for Psychiatric Hospitals (§ 482.61(d))

At § 482.61(d) we propose to clarify the requirement allowing non-physician practitioners to document progress notes in accordance with State laws and scope of practice requirements. We believe this would apportion the burden associated with having MDs/DOs document their progress notes in psychiatric hospitals with non-physician practitioners and will decrease costs associated with this activity. In accordance with the information collection request for the hospital requirements, which includes the special requirements for psychiatric hospitals (OMB control number 0938–0328), no burden is associated with recordkeeping, as the documentation and maintenance of medical records is usual and customary. However, since we believe that clarification of the intent of the regulation is necessary and will result in non-physician practitioners (specifically physician assistants, nurse practitioners, psychologists, and clinical nurse specialists) documenting the progress notes for patients receiving services in psychiatric hospitals, we are attributing ICR burden savings for this provision. For purposes of this analysis only, we estimate that MDs/DOs spend approximately 30 minutes documenting progress notes in psychiatric hospitals. We estimate that 33 percent of this time would be covered by non-physician practitioners. Of the 5,031 Medicare participating hospitals, 574 (or 11 percent) are psychiatric hospitals. According to AHA, there were 35,061,292 inpatient hospital stays in 2015, and an estimated 11 percent of these stays were at psychiatric hospitals. The proposed change would result in a savings of $62.4 million (3,856,742 psychiatric hospital stays × 0.5 hours of physician/psychiatrist time × $98 per hourly wage difference between physicians/psychiatrists ($198) and non-physician practitioners ($100, the average wage between nurse practitioners and physician assistants) × 33 percent of physician time spent writing progress notes covered by non-physician practitioners). This savings is equivalent to $108,647 per psychiatric hospital per year.

O. ICRs Regarding Special Requirement for Transplant Centers and Definitions (§§ 482.68 and 482.70)

We are proposing a nomenclature change at part 482 and the transplant center regulations at §§ 482.68, 482.70, 482.72 through 482.104, and at § 488.61. Because this change would update the terminology used in the regulations to conform to the terminology that is widely used and understood within the transplant community, there are no collection of information requirements associated with this proposal.

P. ICRs Regarding Data Submission, Clinical Experience, and Outcome Requirements for Re-Approval of Transplant Centers (§ 482.82)

Section 482.82 requires that, except as specified in § 488.61, transplant centers must meet all the data submission, clinical experience, and outcome requirements to be re-approved for Medicare participation. Section 482.82(a) requires that no later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of the required data submissions on all transplants (deceased and living donors) it has performed over the 3 year approval period. The required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow up, and living donor registration and follow up. Furthermore, § 482.82(b) requires transplant centers to perform an average of 10 transplants per year during the prior 3 years and § 482.82(c) requires transplant centers to meet the outcome requirements for Medicare re-approval. The burden associated with this requirement would be the time it would take a transplant program to submit the required information. However, as required by §§ 482.72 and 482.45(b), a hospital in which a transplant program is located, must belong to the OPTN, and the OPTN requires that these hospitals submit this data to the OPTN. Therefore, we believe that the requirements under § 482.82 do not impose an additional burden on transplant programs because all Medicare participating transplant programs are already submitting this information to the OPTN. Removing these requirements will have no additional collection of information burden on transplant programs. We describe additional life-saving benefits that result from the removal of this proposal in the subsequent RIA section.

Q. ICRs Regarding Special Procedures for Approval and Re-Approval of Organ Transplant Centers (§ 488.61(f) Through (h))

Section 488.61(f) through (h) sets out the process for our consideration of a transplant center's mitigating factors in initial approval and re-approval surveys, certifications, and enforcement actions for transplant centers. The provisions also set out definitions and rules for transplant systems improvement agreements. We are proposing to remove the requirements at § 488.61(f) through (h) for mitigating

factors and transplant systems improvement agreements for the re-approval process for transplant centers. This change is complementary to the proposed removal of § 482.82, described previously. The information collection request (OMB Control Number 0938–1069) does not account for any information collection related burden associated with the requirements in § 488.61(f) through (h) for the re-approval process. Therefore, we estimate that the requirements under § 488.61(f) would require a transplant program to write and submit the initial formal notice of the program's intent to seek mitigating factors re-approval, and write and submit a request for consideration of mitigating factors (which would include all of the content listed in § 488.61(f)(2)). We estimate that this would take a medical director, a transplant center senior administrator, and a hospital administrator approximately 5 hours, or 2 hours for the medical director and the transplant program senior administrator and 1 hour for the hospital administrator, to complete and submit these mitigating factors for re-approval, as described in Table 2.

TABLE 2—ANNUAL BURDEN HOURS AND COST FOR TRANSPLANT PROGRAMS TO SUBMIT MITIGATING FACTORS FOR RE-APPROVAL

Position	Hourly wage	Hours required	Total cost estimate
Medical Director	$194	2	$388
Transplant Program Senior Administrator	105	2	210
Hospital Administrator	105	1	105
Totals		5	703

In total, we estimate that an average of 14 programs would submit mitigating factors annually. Thus, for those 14 programs we estimate that it would require 70 burden hours (5 burden hours × 14 programs) at a cost of $9,842 ($703 × 14 programs). In the context of this proposed rule, removing this requirement would yield an estimated savings to transplant programs of 5 burden hours each and a total of 70 burden hours for all 14 programs, with a total cost savings of $9,842.

In addition, we estimate that the transplant hospital in conjunction with the transplant program that is located in the hospital, would submit mitigating factors and then would also enter into systems improvement agreements, as described under § 488.61(h) annually. This would require the hospital to enter into a binding agreement with CMS to allow the program additional time to achieve compliance with the CoPs. The agreement would require hospitals to complete certain tasks as listed and described in § 488.61(h)(1), which include (but are not limited to): Patient notification about the degree and type of noncompliance by the program, an explanation of what the program improvement efforts mean for patients and financial assistance to defray the out-of-pocket costs of copayments and testing expenses for any wait-listed individual who wishes to be listed with another program, an external independent peer review team that conducts an onsite assessment of the program, an action plan that addresses systemic quality improvements and is updated after the onsite peer review, an onsite consultant who provides services for 8 days per month on average for the duration of the agreement, a comparative effectiveness analysis that compares policies, procedures, and protocols of the transplant program with those of other programs in areas of endeavor that are relevant to the center's current quality improvement needs, amongst other requirements listed in § 488.61(h)(1)(i) through (x). We estimate that this would take a medical director, a transplant program senior administrator, a hospital administrator, and an administrative assistant approximately 14 hours, or 4 hours for the medical director, transplant program senior administrator, and an administrative assistant, and 2 hours for the hospital administrator to complete these activities (including notifying patients about the degree of noncompliance by mail and organizing and completing the other tasks listed in § 488.61(h)(1) as required by the terms in the systems improvement agreement), as described in Table 3.

TABLE 3—ANNUAL BURDEN HOURS AND COST FOR TRANSPLANT PROGRAMS TO ENTER INTO A SYSTEMS IMPROVEMENT AGREEMENT FOR RE-APPROVAL

Position	Hourly wage	Hours required	Total cost estimate
Medical Director	$194	4	$776
Transplant Program Senior Administrator	105	4	420
Hospital Administrator	105	2	210
Administrative Assistant	34	4	136
Totals		14	1,542

In total, we estimate that an average of 14 programs will submit mitigating factors annually. Thus, for those 14 programs we estimate that it would require 196 burden hours (14 burden hours × 14 programs) at a cost of $21,588 ($1,542 × 14 transplant programs). In the context of this proposed rule, removing this requirement would yield an estimated savings to transplant programs of 14 burden hours each and a total of 196 burden hours for all 14 programs, with a total cost savings of $21,588.

R. ICRs Regarding HHA Home Health Aide Services (§ 484.80(h)(3))

We propose to eliminate the requirement at § 484.80(h)(3) that the HHA conduct a full competency evaluation of deficient home health

aides, and replace it with a requirement to retrain the aide regarding the identified deficient skill(s) and require the aide to complete a competency evaluation related only to those skills. The content of an aide competency examination does not have an associated collection of information requirement. Therefore, this proposed change would neither impose nor remove any collection of information burdens.

S. ICRs Regarding HHA Clinical Records (§ 484.110(e))

We propose to remove the requirement at § 484.110(e) related to providing a requested copy of information contained in the clinical record at the next home visit, while retaining the requirement to provide the record within 4 business days. As stated in the January 2017 HHA CoP final rule (82 FR 4568 and 4575), we believe that providing such information to patients is a usual and customary practice that does not impose a burden upon HHAs and would not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2). As such, removing the ''next home visit'' timeframe requirement would not result in a savings of burden hours or dollars.

T. ICRs Regarding CORF Utilization Review Plan (§ 485.66)

We propose to reduce the required frequency in which CORFs would be required to complete a ''utilization review plan'' from quarterly to annually. Changing from a quarterly implementation of the utilization review plan to an annual implementation would reduce the current documentation requirements (OMB control number 0938–1091) on CORFs by 75 percent each year. For the purposes of our analysis, we estimate that it would take a CORF approximately 8 hours for administrative, clinical and clerical staff to review and evaluate the necessary and efficient use of services provided by the facility on a quarterly basis, for a total of 32 hours per year per CORF and 6,016 hours for all 188 CORFs. In a 1-year period, we estimate a savings of $1,644 per facility ($548 × 3 quarters), and a combined total savings of $309,072 for all CORFs ($1644 × 188 CORFs). We will submit the revised information collection request to OMB for approval.

TABLE 4—CORF—HOURLY WAGES AND BURDEN HOURS

Position	Hourly wage per CORF *	Burden hours per CORF	Cost estimate per CORF
Administrator	$105	2	$210
Clerical Staff	32	2	64
Physical Therapist	84	2	168
Social Worker	53	2	106
Total	274	8	548

* Includes 100% fringe benefits & overhead costs.

U. ICRs Regarding CAH Organizational Structure (§ 485.627(b)(1))

As of May 2017, there were 1,343 CAHs that are certified by Medicare. Our proposed revision of the CAH disclosure requirements imposed on CAHs would remove the requirement for CAHs to disclose to CMS its owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with 42 CFR part 420, subpart C. While we estimate that these changes occur at 2 CAHs per year on average between all 1,343 CAHs, with the vast majority not experiencing any such changes throughout the lifetime of the CAH, each CAH is still required to review the duplicative documentation. In accordance with *Medicare Program; Criteria and Standards for Evaluating Regional Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS); Final Rule and Request for Comments* (57 FR 2790, June 18, 1992), the burden associated with this requirement is 1-hour per facility. As a result, this proposal will save all CAHs an estimated $141,000 and will save each CAH $105 (1-burden hour for an administrator at $105 per hour × 1,343 CAHs). We will submit the revised information collection request to OMB for approval (OMB control number 0938–0328).

V. ICRs Regarding CAH Provision of Services (§ 485.635(a)(4))

Section 485.635(a)(4) requires CAHs to conduct an annual review of all its policies and procedures. Based on feedback from stakeholders, the prescriptive annual schedule is burdensome or, in some situations, ineffective. Our proposed revision of the patient care policies requirements imposed on CAHs would reduce the frequency that is currently required for CAHs to perform a review of all their policies and procedures. We propose that a change from an annual review to a biennial review would reduce the burden on CAHs by half in a given period of time. For the purposes of our analysis, we estimate that it would take a CAH approximately 16 hours for administrative and clinical staff to review and make changes to policies and procedures annually. In a 2-year period, we estimate a savings of $1,956.10 per facility, and a combined total savings of $2.6 million for CAHs ($1,956.10 × 1,343 CAHs).

We estimate that the CAH staff time and associated costs would be assigned to a biennial review as shown in Table 5.

TABLE 5—HOURLY WAGES AND BURDEN HOURS

Position	Hourly wage per CAH	Burden hours per CAH	Cost estimate per CAH
Administrator	$186.88	4	$747.52
Clerical staff	38.78	3	116.34
Registered Nurse	69.40	3	208.20

TABLE 5—HOURLY WAGES AND BURDEN HOURS—Continued

Position	Hourly wage per CAH	Burden hours per CAH	Cost estimate per CAH
Nurse practitioner	100.60	3	301.80
Physician	194.08	3	582.24
Totals	589.74	16	1,956.10

W. ICRs Regarding Special Requirements for CAH Providers of Long-Term Care Services (''Swing-Beds'') (§ 485.645(d)(1), (4), (5) and (8))

We have included the discussion of the ICRs regarding special requirements for CAH providers of long-term care services in the discussion of the ICRs regarding special requirements for hospital providers of long-term care services which can be found under section L of this part.

X. ICRs Regarding CMHCs (§ 485.914(d))

Section 485.914(d)(1) requires each CMHC to update each client's comprehensive assessment via the CMHC interdisciplinary treatment team, in consultation with the client's primary health care provider (if any), no less frequently than every 30 days. We propose to modify the requirement at § 485.914(d) to remove the 30-day assessment update time frame for those clients who do not receive PHP services. Instead of a fixed 30-day time frame, assessment updates would be completed when changes in the client's status, responses to treatment, or goal achievement have occurred, and in accordance with current standards of practice. The burden associated with these requirements is the time required to record an updated assessment. The current information collection request (OMB Control number 0938–1245) does not account for any information collected related to the burden associated with updating the comprehensive assessment requirement. While in the past we believed that this is considered usual and customary practice, recent comments from the CMHC provider community, submitted in response to CMS' solicitation for public comments pertaining to burden reduction suggestions, stated that it is not usual and customary to update assessments for non-PHP clients on a 30 day schedule as required by the CMHC regulations. The commenters stated that the 30 day requirement was overly burdensome, and suggested that the CMHC assessment update requirement should more closely align with the patient-oriented approach of other entities that govern CMHC operations. Upon further consideration, we agreed with the commenter that the 30 day requirement does, in fact, impose a burden and is not usual and customary practice. Therefore, removing this requirement would reduce information collection burden for CMHCs.

Under the current 30-day time frame requirement, each client receives an updated assessment 12 times per year. We estimate that, in accordance with the proposed need-based assessment update requirements, each non-PHP client would receive 2 assessment updates in a year. Therefore, we estimate that this change would reduce the burden of 10 assessments per client, per year.

As of August 2017 there are 52 Medicare participating CMHCs serving 3,122 Medicare beneficiaries and an estimated 2,080 non-Medicare clients, for an average of 100 clients per CMHC. In order to develop the estimated number of non-Medicare clients we divided the total number of Medicare beneficiaries who received partial hospitalization services by the total number of Medicare-participating CMHCs to establish the average number of Medicare beneficiaries per CMHC. This resulted in 60 beneficiaries per CMHC. We then assumed that, in order to comply with the 40 percent requirement (§ 485.918(b)(1)(v)), those 60 beneficiaries only accounted for 60 percent of an average CMHC's total patient population. This means that an average CMHC also treated another 40 clients who did not have Medicare as a payer source, for a total of 100 clients (Medicare + non-Medicare) in an average CMHC. Therefore, all CMHCs combined would have approximately 2,080 non-PHP clients per year (40 per CMHC), and approximately 20,800 assessments would be reduced nationwide per year (2,080 patients × 10 assessments per patient). We estimate that documenting each assessment update requires 10 minutes of a CMHC clinician's time, for a total savings of 3,466 hours nationwide (1,666 hours × 20,800 assessment updates). At a cost of $7.33 for a mental health counselor to document each assessment, the total cost savings would be $152,464 ($7.33 × 20,800 assessments).

Y. ICRs Regarding Portable X-Ray Services (§§ 486.104(a) and 486.106(a))

We propose to revise the requirements for portable x-ray technologist personnel qualifications at § 486.104 to align the current requirements at § 486.104(a)(1), (2), (3), and (4) with those for hospital radiologic technologists at § 482.26(c)(2) which are focused on the qualifications of the individual performing services as permitted by State law. Although changing the qualifications would require management time, with the associated cost of those hours, in order to revise the internal personnel descriptions and qualifications, we believe that this proposed change would impose no burden because maintaining internal personnel descriptions and qualifications is a standard business practice. Therefore, this burden would not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

We propose to revise the requirements for portable x-ray orders at § 486.106(a)(2). We propose to remove the requirement that physician or non-physician practitioner's orders for portable x-ray services must be written and signed. We also propose to replace the specific requirements related to the content of each portable x-ray order with a cross-reference to the requirements at 42 CFR 410.32, which also apply to portable x-ray services. These proposed changes would simplify the ordering process for portable x-rays and promote the use of more efficient ordering methods, such as electronic orders.

This change would allow for portable x-ray services to be ordered in writing, by telephone, or by electronic methods. The change would also streamline the ordering process by avoiding the need to write two separate orders for the same study, one to meet the Medicare payment requirements in accordance with § 410.32 and its associated Manual guidance, and another to meet the content requirements of the regulation set forth at § 486.106. We believe the proposed change would allow for additional ordering flexibility to streamline ordering practices. In the information collection request (OMB control number 0938–0338) we estimate

that the current order requirements would impose the following burdens:

- 3 minutes to write an order × 3,986,000 portable x-rays exams ordered = 199,300 hours × $69/hour for a nurse = $13,751,700.
- $1 for printing and faxing verbal orders to physician offices for signature × 2,500,000 verbal orders = $2,500,000.
- 2,000,000 follow-up calls regarding the status of faxes × 10 minutes of time for clerical staff (5 minutes for portable x-ray clerical staff + 5 minutes for ordering physician clerical staff) = 333,333 hours × $32/hour = $10,666,656.

All of these burdens would be eliminated by revising the current ordering standards. Therefore, we estimate a proposed information collection savings of $26,918,356 from this proposed change.

Z. ICRs Regarding RHC and FQHC Provision of Services (§ 491.9(b)(4))

There are currently more than 4,100 RHCs and approximately 1,400 FQHC organizations furnishing services at approximately 12,000 or more total locations. Many FQHC organizations have multiple delivery sites, so to be as accurate as possible, our burden reduction calculations are based on the most recent data available, which shows that as of May 2017, there were 4,160 RHCs and 7,874 FQHC delivery sites. All CMS-certified sites are subject to our requirements and we are therefore utilizing the total number of current sites in our burden reduction calculations.

We propose to revise § 491.9(b)(4) to reduce the number of times that RHCs and FQHCs perform a review of all their policies and procedures. Changing from an annual review to a review every other year would reduce the burden on RHCs and FQHCs by half in a given period of time. In the currently approved information collection request (OMB control number 0938–0334), we estimate that it would take a RHC or FQHC approximately 4 hours for clinical staff to review and make changes to policies and procedures annually, for a total of 48,136 hours for all 12,034 RHC and FQHC locations. In a 2-year period, RHCs and FQHCs would use 96,272 total hours to comply with the requirements to annually review all of their policies and procedures. Under the proposed change to a review every other year, we estimate that in a 2-year period, it will take a total of 48,136 hours, for a savings of 48,136 hours per year. We estimate a savings of $592 per facility (see Table 6) for a combined total savings of $7.1 million for 12,034 RHCs or FQHCs ($592 × 12,034 RHCs and FQHCs). We will submit a revised information collection request to OMB for approval.

TABLE 6—HOURLY WAGES AND BURDEN HOURS

Position	Hourly wage per RHC/FQHC (Includes 100% benefit package)	Burden hours per RHC/FQHC	Cost estimate per RHC/FQHC
Physician	$198	2	$396
Mid-Level Provider (PA or NP)	98	2	196
Total	296	4	592

AA. ICRs Regarding RHC and FQHC Program Evaluation (§ 491.11(a))

We propose to revise § 491.11(a) to reduce the number of times that RHCs and FQHCs carry out or arrange for an annual evaluation of the total program. Changing from an annual evaluation to an evaluation every other year would reduce the burden on RHCs and FQHCs by half in a given period of time. In the currently approved information collection request (OMB control number 0938–0334), we estimate that it would take a RHC or FQHC approximately 6 hours for administrative and clinical staff to perform an evaluation of its total program annually for a total of 72,204 hours for all 12,034 RHC and FQHC locations. In a 2-year period, RHCs and FQHCs would use 144,408 total hours to comply with the requirement for an evaluation of the total program. Under the proposed change to evaluate the total program every other year, we estimate a hourly savings of 72,204 total hours and a cost savings of $802 per facility (see Table 7), for a combined total savings of $9.7 million for 12,034 RHCs or FQHCs ($802 × 12,034 RHC and FQHC locations).

TABLE 7—HOURLY WAGES AND BURDEN HOURS

Position	Hourly wage per RHC/FQHC (Includes 100% benefit package)	Burden hours per RHC/FQHC	Cost estimate per RHC/FQHC
Administrator/Health Services Manager	$105	2	$210
Physician	198	2	396
Mid-Level Provider (PA or NP)	98	2	196.00
Total	401	6	802

BB. ICRs Regarding Emergency Preparedness for Providers and Suppliers

1. Review of the Emergency Preparedness Program

At § 482.15(a), (b), (c), and (d) for hospitals and parallel regulatory citations for other facilities, we propose to allow providers to review their program at least every 2 years. As of May 2017, there were approximately 74,246 total facilities. All are required to review their emergency preparedness program annually, which includes a review of their emergency plan, policies and procedures, communication plan, and training and testing program.

For our analysis, we estimate that reducing this requirement from annually to biennially would reduce compliance costs related to review of the emergency plan by 50 percent. The methodology used for our cost estimate analysis generally mirrors the methodology used for the annual review of the emergency plan Emergency Preparedness final rule (81 FR 63930) with a 50 percent reduction in the cost estimate calculation; however, after receiving additional feedback from stakeholders, we have determined that we underestimated the amount of time it would take to review the emergency plan. As a result, we have presented current burden hours associated with reviewing the emergency plan that reflects the increased associated burden hours relative to the information collection request for this provision (OMB control number 0938–1325). As in the Emergency Preparedness final rule (81 FR 63930), we assume that the individuals involved in the review of the emergency plan include an administrator, director of nursing, a RN, a physician, a social worker, a counselor, and an office manager, depending on the facility type. Based on May 2016 BLS salary data, we calculated the hourly mean wage for each position for this requirement identified in the Emergency Preparedness final rule (81 FR 63930).

We estimate that the proposed change will accrue a total annual cost savings of $94,312,719 and 187 burden hours saved. We list a detailed calculation for each facility below, based on facility numbers available as of May 2017:

- *RNHCIs:* Combined total savings of $9,540 for 18 RNHCIs ((8 burden hours for an administrator at $105 plus 5 burden hours for a director of nursing at $44 per hour) × 18 RNHCIs × 50 percent).
- *ASCs:* Combined total savings of $6,134,928 for 5,557 ASCs ((8 burden hours for an administrator at $108 per hour plus 4 burden hours for a physician at $198 per hour plus 8 burden hours for a quality improvement RN at $69 per hour) × 5,557 ASCs × 50 percent).
- *Hospices:* Combined total savings of $5,781,832 for 4,489 hospice facilities ((8 burden hours for an administrator at an hourly wage of $105 per hour plus 4 burden hours for a physician at $198 per hour plus 4 burden hours for a counselor at $44 per hour plus 4 burden hours for a social worker at $54 per hour plus 8 burden hours for a RN at $69 per hour) × 4,489 hospices × 50 percent).
- *PRTFs:* Combined total savings of $556,512 for 374 PRTFs ((8 burden hours for an administrator $105 per our plus 8 burden hours for a physician at $198 per hour plus 8 burden hours for a RN at $69 per hour) × 374 PRTFs × 50 percent).
- *PACE:* Combined total savings of $226,476 for 233 PACE organizations ((8 burden hours for an administrator at $105 per hour plus 8 burden hours for a home care coordinator at $69 per hour plus 8 burden hours for a RN at $69 per hour) × 233 PACE organizations × 50 percent).
- *Hospitals:* Combined total savings of $11,933,532 for 5,031 hospitals ((8 burden hours for an administrator at $108 per hour plus 8 burden hours for a physician at $198 per hour plus 8 burden hours for a risk management director at $105 per hour plus 8 burden hours for a quality assurance nurse at $69 per hour plus 8 burden hours for a facility director at $96 per hour plus 4 burden hours for a medical secretary at $34 per hour) × 5,031 hospitals × 50 percent).
- *LTCF:* Combined total savings of $25,562,016 for 15,663 LTCF facilities ((8 burden hours for an administrator at $105 per hour plus 8 burden hours for a physician at $198 per hour plus 8 burden hours for a director of nursing at $105 per hour) × 15,663 LTCFs × 50 percent).
- *ICF/IID:* Combined total savings $3,402,126 for 6,097 ICF/IIDs ((8 burden hours for an administrator at $105 per hour plus 4 burden hours for a RN $69 per hour) × 6,097 ICF/IIDs × 50 percent).
- *HHA:* Combined total savings of $16,259,712 for 12,624 HHAs ((8 burden hours for an administrator at $105 per hour plus 8 burden hours for a nursing director at $105 per hour plus 8 burden hours for a director of rehab at $84 per hour plus 4 burden hours for an office manager at $56 per hour) × 12,624 HHAs × 50 percent).
- *CORF:* Combined total savings of $142,128 for 188 CORFs ((8 burden hours for an administrator at $105 per hour plus 8 burden hours for a physical therapist at $84 per hour) × 188 CORFs × 50 percent).
- *CAH:* Combined total savings of $1,643,832 for 1,343 CAHs ((8 burden hours for an administrator at $105 per hour plus 8 burden hours for a director of nursing at $105 per hour plus 8 burden hours for a facility director at $96 per hour) × 1,343 CAHs × 50 percent).
- *Organizations:* Combined total savings of $1,220,688 for 2,076 Organizations ((8 burden hours for an administrator at $105 per hour plus 4 burden hours for a physical therapist at $84 per hour) × 2,076 Organizations × 50 percent).
- *CMHCs:* Combined total savings of $146,832 for 161 CMHCs ((8 burden hours for an administrator at $105 per hour plus 8 burden hours for a RN at $69 per hour plus 8 burden hours for a social worker at $54 per hour) × 161 CMHCs × 50 percent).
- *OPOs:* Combined total savings of $119,016 for 58 OPOs ((8 burden hours for an OPO director at $105 per hour plus 8 burden hours for a physician at $198 per hour plus 8 burden hours for a QAPI director at $105 per hour plus 8 burden hours for an organ procurement coordinator at $105 per hour) × 58 OPOs × 50 percent).
- *RHC/FQHC:* Combined total savings of $9,916,016 ((8 burden hours for an administrator at $105 per hour plus 8 burden hours for a nurse practitioner/physician assistant at $101 per hour) × 4,160 RHCs × 50 percent) $3,427,840 + ((8 burden hours for an administrator at $105 per hour plus 8 burden hours for a nurse practitioner/physician assistant at $101 per hour × 7,874 FQHCs × 50 percent) $6,488,176).
- *ESRD Facilities:* Combined total savings of $11,064,392 for 6,898 dialysis facilities ((8 burden hours for an administrator at $105 per hour plus 8 burden hour for a medical director/physician at $198 per hour plus 8 burden hours for a nurse manager at $105) × 6,898 dialysis facilities × 50 percent) as shown in Table 8.

TABLE 8—COST SAVINGS FOR ANNUAL REVIEW OF EMERGENCY PREPAREDNESS PLAN

Provider/supplier	Cost savings per provider/ supplier	Combined total savings
RNHCIs	$530	$9,540 for 18 RNHCIs.
ASCs	1,104	$6,134,928 for 5,557 ASCs.
Hospices	1,288	$5,781,832 for 4,489 hospice facilities both inpatient and freestanding/home based.
PRTFs	1,488	$556,512 for 374 PRTFs.
PACEs	972	$226,476 for 233 PACEs.
Hospitals	2,372	$11,933,532 for 5,031 hospitals.
LTCFs	1,632	$25,562,016 for 15,663 LTCFs.
ICFs/IIDs	558	$3,402,126 for 6,097 ICF/IIDs.
HHAs	1,288	$16,259,712 for 12,624 HHAs.
CORFs	756	$142,128 for 188 CORFs.
CAHs	1,224	$1,643,832 for 1,343 CAHs.
Organizations	588	$1,220,688 for 2,076 Organizations.
CMHCs	912	$146,832 for 161 CMHCs.
OPOs	2,052	$119,016 for 58 OPOs.
RHCs/FQHCs	824	$9,916,016 for RHCs and FQHCs ($3,427,840 for 4,160 RHCs and $6,488,176 for 7,874 FQHCs).
ESRD Facilities	1,6332	$11,257,536 for 6,898 dialysis facilities.

2. Contents of the Emergency Plan

At § 482.15(a)(4) for hospitals, and other parallel citations for the facilities mentioned in section II.J.2 of this proposed rule, we propose to eliminate the requirement that facilities document efforts to contact local, tribal, regional, State, and Federal emergency preparedness officials and that facilities document participation in collaborative and cooperative planning efforts. We estimate that an administrator, or in the case of a hospital a community relations manager, a program director for a PACE, or a QAPI director for OPOs, would take 1 hour to document efforts to contact local, tribal, regional, State and Federal emergency preparedness officials and, when applicable, document the facility's participation in collaborative and cooperative planning efforts. We note that the Joint Commission (TJC)-accredited ASCs, TJC-accredited CAHs, and TJC-accredited hospitals have emergency preparedness requirements for developing an emergency preparedness plan that are comparable to the current emergency preparedness CoPs (81 FR 63937, 63954, and 63978 through 63979). Utilizing the same assumptions we used in the Emergency Preparedness final rule (81 FR 63937, 63954, and 63978 through 63979), we estimate that cost savings will accumulate from non-TJC accredited ASC, CAHs, and hospitals, since TJC-accredited ASCs, CAHs and hospitals are already required by the TJC to develop emergency preparedness plans. As a result, these facilities are excluded from the analysis given the requirements of their accreditation organization standards. Based on May 2016 BLS salary data, we calculate an hourly mean wage of $105 for an administrator, a PACE Program Director, or QAPI director and a cost savings of $105 per facility for RNHCIs, non-TJC accredited ASCs, hospices (both inpatient and freestanding), PRTFs, PACEs, LTCFs, ICF/IIDs, HHAs, CORFs, non-TJC accredited CAHs, Organizations, CMHCs, OPOs, RHC/FQHCs, and dialysis facilities ($105 hourly mean wage × 1 burden hour). For non-TJC accredited hospitals, we estimate an hourly mean wage of $114 for a community relations manager, and a $114 cost per facility ($114 × 1 hour). Therefore, we estimate the following for each facility affected by the proposed change, for a total savings of $7,179,117 and 18 burden hours. We list a summary of the calculation for savings accrued by removing this requirement for each facility in Table 9, based on facility numbers available as of May 2017.

TABLE 9—COST SAVINGS: DOCUMENTATION OF THE FACILITY'S PARTICIPATION IN COLLABORATIVE AND COOPERATIVE PLANNING EFFORTS

Provider/supplier	Cost savings per provider/ supplier	Combined total savings
RNHCIs	$105	$1,890 for 18 RNHCIs.
ASCs (Non-TJC accredited)	105	$522,375 for 4,975 non-TJC accredited ASCs.
Hospices	105	$471,345 for 4,489 hospice facilities both inpatient and freestanding/home based.
PRTFs	105	$39,270 for 374 PRTFs.
PACEs	105	$24,465 for 233 PACEs.
Hospitals (Non-TJC accredited)	114	$157,662 for 1,383 non-TJC accredited hospitals.
LTCFs	105	$1,644,615 for 15,663 LTCFs.
ICFs/IIDs	105	$640,185 for 6,097 ICF/IIDs.
HHAs	105	$1,325,520 for 12,624 HHAs.
CORFs	105	$19,740 for 188 CORFs.
CAHs (Non-TJC accredited)	105	$103,215 for 983 non-TJC accredited CAHs.
Organizations	105	$217,980 for 2,076 Organizations.
CMHCs	105	$16,905 for 161 CMHCs.
OPOs	105	6,090 for 58 OPOs.
RHCs/FQHCs	105	$1,263,570 for RHCs and FQHCs ($436,800 for 4,160 RHCs and $826,770 for 7,874 FQHCs).

TABLE 9—COST SAVINGS: DOCUMENTATION OF THE FACILITY'S PARTICIPATION IN COLLABORATIVE AND COOPERATIVE PLANNING EFFORTS—Continued

Provider/supplier	Cost savings per provider/ supplier	Combined total savings
ESRD Facilities	105	$724,290 for 6,898 dialysis facilities.

3. Training

At § 482.15(d)(1)(ii) for hospitals, and other parallel citations for other facilities mentioned in section II.J.2 of this proposed rule, we propose to require that facilities provide training biennially, or every 2 years, after facilities conduct initial training on their emergency program. In addition, we propose to require additional training when the emergency plan is significantly updated. We believe that the annual training requirement is too prescriptive as annual may not always be necessary. We propose to maintain the requirement that providers and suppliers develop a well-organized, effective training program that includes initial training for new and existing staff in emergency preparedness policies and procedures and would require training when the emergency plan is significantly updated. Facilities would have the flexibility to determine what is considered a significant update to the emergency plan.

For our analysis, we estimate that reducing this requirement from annually to biennially will reduce compliance costs related to providing emergency preparedness training by 50 percent. The methodology used for our cost estimate analysis mirrors the methodology used for the annual training requirement in the Emergency Preparedness final rule (81 FR 63930) with a 50 percent reduction in the cost estimate calculation. As in the Emergency Preparedness final rule (81 FR 63930), we assume that the individuals involved in the development and provision of training include an administrator, director of nursing, a RN, and an office manager, depending on the facility type. Providers and suppliers are expected to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Based on May 2016 BLS salary data, we calculated the hourly mean wage for each position for this requirement identified in the Emergency Preparedness final rule (81 FR 63930). We estimate that the proposed change will accrue a total annual cost savings of $33,267,864 and 111 burden hours. We list a detailed calculation for each facility below, based on facility numbers available as of May 2017 with a summary of these calculations provided in Table 10:

- *RNHCIs:* Combined total savings of $3,870 for 18 RNHCIs ((2 burden hours for an administrator at $105 plus 5 burden hours for a director of nursing at $44 per hour) × 18 RNHCIs × 50 percent).
- *ASCs:* Combined total savings of $1,258660 for 5,557 ASCs ((1 burden hour for an administrator at $108 per hour plus 5 burden hours for a quality improvement RN at $69 per hour) × 5,557 ASCs × 50 percent).
- *Hospices:* Combined total savings of $929,223 for 4,489 hospice facilities (6 burden hours for a RN at $69 per hour × 4,489 hospices × 50 percent).
- *PRTFs:* Combined total savings of $129,030 for 374 PRTFs (10 burden hours for a RN at $69 per hour × 374 PRTFs × 50 percent).
- *PACE:* Combined total savings of $96,462 for 233 PACE organizations (3 burden hours for a home care coordinator at $69 per hour plus 9 burden hours for a RN at $69 per hour × 233 PACE organizations × 50 percent).
- *Hospitals:* As we stated in the Emergency Preparedness final rule (81 FR 63958), TJC-accredited hospitals are required to train their staff for their assigned roles during emergencies (CAMH, Standard EC.4.16, Eps 1–2, p. EC–13e). In addition, the TJC-accredited hospitals also must provide on-going training to their staff, including training on specific job-related safety (CAMH, Standard HR–2.30, EP 4, CAMH Refreshed Core, January 2008, p. HR–11), and we expect that emergency preparedness is part of such on-going training. As a result, we estimate a combined total savings of $2,015,031 for 1,383 non-TJC accredited hospitals (2 burden hours for an administrator at $108 per hour plus 6 burden hours for a risk management director at $105 per hour plus 28 hours for a healthcare trainer (RN) at $69 per hour plus 4 burden hours for a medical secretary at $34 per hour × 1,383 hospitals × 50 percent).
- *LTCF:* Combined total savings of $8,223,075 for 15,663 LTCFs (2 burden hours for an administrator at $105 per hour plus 8 burden hours for a director of nursing at $105 per hour × 15,663 LTCFs × 50 percent).
- *ICF/IID:* Combined total savings $1,691,918 for 6,097 ICF/IIDs (2 burden hours for an administrator at $105 per hour plus 5 burden hours for a RN $69 per hour × 6,097 ICF/IIDs × 50 percent).
- *HHA:* Combined total savings of $7,902,624 for 12,624 HHAs (2 burden hours for an administrator at $105 per hour plus 2 burden hours for a nursing director at $105 per hour plus 2 burden hours for a director of rehab at $84 per hour plus 2 burden hours for an office manager at $56 per hour plus 8 burden hours for a director of training at $69 × 12,624 HHAs × 50 percent).
- *CORF:* Combined total savings of $73,038 for 188 CORFs (5 burden hours for an administrator at $105 per hour plus 3 burden hours for a physical therapist at $84 per hour × 188 CORFs × 50 percent).
- *CAH:* Combined total savings of $968,974 for 1,343 CAHs (2 burden hours for an administrator at $105 per hour plus 9 burden hours for a director of nursing at $105 per hour plus 3 burden hours for a facility director at $96 per hour × 1,343 CAHs × 50 percent).
- *Organizations:* Combined total savings of $828,324 for 2,076 Organizations (6 burden hours for an administrator at $105 per hour plus 2 burden hours for a physical therapist at $84 per hour × 2,076 Organizations × 50 percent).
- *CMHCs:* Combined total savings of $55,545 for 161 CMHCs (10 burden hours for a psychiatric RN at $69 per hour × 161 CMHCs × 50 percent).
- *OPOs:* Combined total savings of $111,012 for 58 OPOs (2 burden hours for a director at $114 per hour plus 2 burden hours for a medical director/ physician at $198 per hour plus 12 burden hours for a QAPI director at $105 per hour plus 8 hours for an organ procurement coordinator at $105 per hour plus 16 burden hours for an education coordinator at $69 per hour × 58 OPOs × 50 percent).
- *RHC/FQHC:* Combined total savings of $6,125,306 ((2 burden hours for an

administrator at $105 per hour plus 8 burden hours for a nurse practitioner/physician assistant at $101 per hour × 4,160 RHCs × 50 percent) $2,117,440 + (2 burden hours for an administrator at $105 per hour plus 8 burden hours for a nurse practitioner/physician assistant at $101 per hour × 7,874 FQHCs × 50 percent) $4,007,866).

• *ESRD Facilities:* Combined total savings of $2,855,772 for 6,898 dialysis facilities (3 burden hours for an administrator at $105 per hour plus 1 burden hour for a medical director/physician at $198 per hour plus 3 burden hours for a nurse manager at $105 × 6,898 dialysis facilities × 50 percent).

TABLE 10—COST SAVINGS: TRAINING

Provider/supplier	Cost savings per provider/supplier	Combined total savings
RNHCIs	$215	$3,870 for 18 RNHCIs.
ASCs	226	$1,258,660 for 5,557 ASCs.
Hospices	207	$929,223 for 4,489 hospice facilities both inpatient and freestanding/home based.
PRTFs	345	$129,030 for 374 PRTFs.
PACEs	414	$96,462 for 233 PACE organizations.
Hospitals (Non-TJC accredited)	1,457	$2,015,031 for 1,383 non-TJC accredited hospitals.
LTCFs	525	$8,223,075 for 15,663 LTCFs.
ICFs/IIDs	278	$1,691,918 for 6,097 ICF/IIDs.
HHAs	626	$ 7,902,624 for 12,624 HHAs.
CORFs	389	$73,038 for 188 CORFs.
Organizations	399	$828,324 for 2,076 Organizations.
CAHs	721	$968,974 for 1,343 CAHs.
CMHCs	345	$55,545 for 161 CMHCs.
OPOs	1,914	$1111,012 for 58 OPOs.
RHCs/FQHCs	509	$6,125,306 for RHCs and FQHCs ($2,117,440 for 4,160 RHCs and $4,007,866 for 7,874 FQHCs).
ESRD Facilities	414	$2,855,772 for 6,898 dialysis facilities.

4. Testing

Finally, at § 482.15(d)(2), we propose to require that providers of inpatient services mentioned in section II.J.2 of this proposed rule conduct two testing exercises annually, one of which may be an exercise of their choice that must be either a community-based full-scale exercise (if available), an individual facility-based functional exercise, a drill, a tabletop exercise or workshop that includes a group discussion led by a facilitator. We estimate that revising this requirement to include additional options for the types testing exercises that may be conducted for one of the two annually required exercises will provide greater flexibility for these providers. Given that these providers are currently required to conduct two testing exercises annually, and because they may choose to conduct the same types of testing exercises, we do not anticipate that this requirement will impose a burden upon providers of inpatient services and as such, this revision would not result in a savings of burden hours or dollars.

We propose to require that providers of outpatient services mentioned in section II.J.2 of this proposed rule conduct one testing exercise annually which must be either a community-based full-scale exercise (if available) or an individual facility-based functional exercise every other year, and in the opposite years, may be either a community-based full-scale exercise (if available), a facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator.

For our analysis, we estimate that reducing this requirement from biannually to annually for outpatient providers will reduce compliance costs related to conducting emergency preparedness testing by 50 percent. The methodology used for our cost estimate analysis mirrors the methodology used for the biannual testing requirement in the Emergency Preparedness final rule (81 FR 63930) with a 50 percent reduction in the cost estimate calculation. As in the Emergency Preparedness final rule (81 FR 63930), we will assume that the same individuals involved with developing training would typically also develop the scenarios, materials, as well as any accompanying documentation associated with testing exercises. Based on May 2016 BLS salary data, we calculated the hourly mean wage for each position for this requirement identified in the Emergency Preparedness final rule (81 FR 63930) and decreased the cost by 50 percent due to the 50 percent reduction in the frequency requirement.

We estimate that the proposed change will accrue a total annual cost savings of $9,117,425 and 25 burden hours. We list a detailed calculation for each facility below, based on facility numbers available as of May 2017 with a summary of these calculations provided in Table 11:

• *ASCs:* Combined total savings of $1,066,944 for 5,557 ASCs ((1 burden hour for an administrator at $108 per hour plus 4 burden hours for a quality improvement RN at $69 per hour) × 5,557 ASCs × 50 percent).

• *Freestanding/home-based hospices:* Combined total savings of $557,520 for 4,040 hospice facilities (4 burden hours for a RN at $69 per hour × 4,040 hospices × 50 percent).

• *PACE:* Combined total savings of $40,193 for 233 PACE organizations (4 burden hours for a home care coordinator at $69 per hour plus 1 burden hours for a RN at $69 per hour × 233 PACE organizations × 50 percent).

• *HHA:* Combined total savings of $3,970,248 for 12,624 HHAs (1 burden hour for an administrator at $105 per hour plus 3 burden hours for a nursing director at $105 per hour plus 1 burden hours for a director of rehab at $84 per hour plus 1 burden hour for an office manager at $56 per hour plus 1 burden hours for a director of training at $69 × 12,624 HHAs × 50 percent).

• *CORF:* Combined total savings of $55,272 for 188 CORFs (4 burden hours for an administrator at $105 per hour plus 2 burden hours for a physical therapist at $84 per hour × 188 CORFs × 50 percent).

• *Organizations:* Combined total savings of $305,172 for 2,076 organizations (2 burden hours for an administrator at $105 per hour plus 1

burden hour for a physical therapist at $84 per hour × 2,076 organizations × 50 percent).

• *CMHCs:* Combined total savings of $22,218 for 161 CMHCs (4 burden hours for a psychiatric RN at $69 per hour × 161 CMHCs × 50 percent).

• *OPOs:* Combined total savings of $12,673 for 58 OPOs (3 burden hours for a QAPI director at $105 per hour plus 2 burden hours for an education coordinator at $69 per hour × 58 OPOs × 50 percent).

• *RHC/FQHC:* Combined total savings of $3,086,721 ((2 burden hours for an administrator at $105 per hour plus 3 burden hours for a nurse practitioner/physician assistant at $101 per hour × 4,160 RHCs × 50 percent) + (2 burden hours for an administrator at $105 per hour plus 3 burden hours for a nurse practitioner/physician assistant at $101 per hour × 7,874 FQHCs × 50 percent)).

• *ESRD:* As identified in the Emergency Preparedness final rule (81 FR 64006), the current CFCs already require dialysis facilities to evaluate their emergency preparedness plan at least annually (§ 494.60(d)(4)(ii)); thus, we expect that all dialysis facilities are already conducting some type of tests to evaluate their emergency preparedness plans. As a result, ESRDs are not included in the burden calculation.

TABLE 11—COST SAVINGS: TESTING

Provider/supplier	Cost savings per provider/ supplier	Combined total savings
ASCs	$192	$1,066,944 for 5,557 ASCs.
Hospices (freestanding/home-based)	138	$557,520 for 4,040 hospices.
PACEs	173	$40,193 for 233 PACE organizations.
HHAs	314	$3,970,248 for 12,624 HHAs.
CORFs	294	$55,272 for 188 CORFs.
Organizations	147	$305,172 for 2,076 Organizations.
CMHCs	138	$22,218 for 161 CMHCs.
OPOs	226	$13,137 for 58 OPOs.
RHCs/FQHCs	256	$3,086,721 ($1,067,040 for 4,160 RHCs and $2,019,681 for 7,874 FQHCs).

We will submit a revised information collection request to OMB to account for the burden hour and cost savings.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

All major and many ostensibly minor government regulations should undergo periodic review to ensure that they do not unduly burden regulated entities or the American people, and reflect current knowledge as to regulatory effects. In recent years, we have revised the CoPs and CfCs to reduce the regulatory burden on providers and suppliers. In doing so, we identified obsolete and burdensome regulations that could be eliminated or reformed to improve effectiveness or reduce unnecessary reporting requirements and other costs, with a particular focus on freeing up resources that health care providers, health plans, and States could use to improve or enhance patient health and safety. We also examined policies and practices not codified in rules that could be changed or streamlined to achieve better outcomes for patients while reducing burden on providers of care, and we identified non-regulatory changes that would increase transparency and allow CMS to become a better business partner. In accordance with these goals, we published three final rules that identified unnecessary, obsolete, or excessively burdensome regulations on health care providers, suppliers, and beneficiaries. These rules further increased the ability of health care professionals to devote resources to improving patient care by eliminating or reducing requirements that impede quality patient care or that divert providing high quality patient care:

• ''Reform of Hospital and Critical Access Hospital Conditions of Participation'', published May 16, 2012 (77 FR 29034);

• ''Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction'', published May 16, 2012 (77 FR 29002) and;

• ''Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II'', published May 12, 2014 (79 FR 27105).

These reforms, however, did not exhaust the potential for burden-reducing reforms. We have continued to consult with regulated entities, have reviewed new research findings, have reviewed comments on previous rulemakings, and in these and other ways have identified additional reforms. These reforms are addressed in this proposed rule.

This proposed rule is not just a continuation of our efforts to reduce regulatory burden but also directly responds to the January 30, 2017 Executive Order ''Reducing Regulation and Controlling Regulatory Costs'' (Executive Order 13771). We propose changes to the current CoPs or CfCs that will simplify and streamline the current regulations and thereby increase provider flexibility and reduce excessively burdensome regulations, while also allowing providers to focus on providing high-quality healthcare to their patients. This proposed rule will also reduce the frequency of certain required activities and, where appropriate, revise timelines for certain requirements for providers and suppliers and remove obsolete, duplicative, or unnecessary requirements. Ultimately, these proposals balance patient safety and quality, while also providing broad regulatory relief for providers and suppliers, and reducing the associated burden on patients.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995

(March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, presents the costs and benefits of the rulemaking.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget. This proposed rule would create ongoing cost savings to providers and suppliers in many areas. Other changes we have proposed would clarify existing policy and relieve some administrative burdens. We have identified other kinds of savings that providers and patients will realize throughout this preamble, and substantial lifesaving benefits. These life-saving effects arise by removing the incentives created by the current transplant center regulations to decline to transplant patients with slightly lower probability of success, and to decline to use organs with a slightly lower probability of success.

We welcome public comments on all of our burden assumptions and estimates as well as comments identifying additional reforms that should be considered for future rulemakings. As discussed later in this regulatory impact analysis, substantial uncertainty surrounds these estimates and we especially solicit comments on either our estimates of likely impacts or the specific regulatory changes that drive these estimates.

As stated in the ICR section of this proposed rule, we obtained all salary information from the May 2016 National Occupational Employment and Wage Estimates, United States by the Bureau of Labor Statistics (BLS) at *https://www.bls.gov/oes/2016/may/oes_nat.htm* and calculated the added value of 100 percent for overhead and fringe benefits.

TABLE 12—SECTION–BY–SECTION ECONOMIC IMPACT ESTIMATES

Provider and supplier type and description of proposed provisions	Frequency	Number of affected entities	Estimated annual savings or benefits ($ millions)
Religious Nonmedical Health Care Institutions:			
• Discharge Planning	As patients are discharged (Estimated 619 annual discharges).	18	*
Ambulatory Surgical Centers:			
• Governing Body and Management	Upon failed hospital transfer agreement attempts.	5,557	*
• Patient Admission, Assessment and Discharge (History and Physical).	Every patient registration at an ASC or at a hospital outpatient/ambulatory surgery department.	5,557 (ASCs) 5,031 (Hospitals)	454
• Medical Records	Recurring annually	5,557	0
Hospices:			
• Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment.	Recurring annually	1,151	80
• Hospices That Provide Hospice Care to residents of a SNF/NF or ICF/IID.	Recurring annually	4,602	*
• Hospice Aide and Homemaker Services	Recurring annually	3,498	2
Hospitals:			
• Quality Assessment and Performance Improvement Program.	Recurring annually	5,031	28
• Medical staff: Autopsies	Recurring annually	5,031	0
• Infection Control	Recurring annually	5,031	105
• Special requirements for hospital providers of long-term care services (''swing-beds'').	Recurring annually	1,724	30
• Special Requirements for Psychiatric Hospitals	Recurring annually	574	62
Transplant programs:			
• Various provisions related to performance**	Recurring annually	750	Not Quantified
Home Health Agencies:			
• Patient rights	Recurring annually	12,624	55
• Home health aide services	Recurring annually	12,624	0
• Clinical records	Recurring annually	12,624	0
Critical Access Hospitals:			
• Provision of Services	Recurring biennially	1,343	2
• Organizational structure	Recurring annually	1,343	*

TABLE 12—SECTION–BY–SECTION ECONOMIC IMPACT ESTIMATES—Continued

Provider and supplier type and description of proposed provisions	Frequency	Number of affected entities	Estimated annual savings or benefits ($ millions)
• Special requirements for CAH providers of long-term care services (''swing-beds'').	Recurring annually	1,246	86
Comprehensive Outpatient Rehabilitation Facilities:			
• Utilization Review Plan	Recurring annually	188	*
Community Mental Health Centers:			
• Assessment Update	Recurring annually	52	*
Portable X-Ray Services:			
• Qualifications of X-ray technicians***	Annual	500	31
• Removing written orders	Annual	500	29
RHC (4,160 clinics) & FQHC (7,874 center locations):			
• Provision of Services	Recurring biennially	12,034	7
• Program Evaluation	Recurring biennially	12,034	9
Emergency Preparedness for Providers and Suppliers:			
• Annual Review of Emergency Preparedness Program	Recurring annually	72,844	94
• Emergency Plan	Recurring annually	68,254	7
• Training and Testing-Training Program	Recurring annually	69,196	33
• Training and Testing-Testing	Recurring annually	36,971	9
Total Annual Savings			1,123
Life-extending benefits for transplant patients			Not Quantified

*Amount is less than one million dollars.
**These include proposed changes to the following requirements: Special Requirements for Transplant Programs; Data submission, Clinical Experience, and Outcome Requirement for Re-approval of Transplant Programs; and Special Procedures for Approval and Re-Approval of Organ Transplant Programs.
***This estimate is for first full year savings only and will increase in future years.

C. Anticipated Effects

1. Effects on Religious Nonmedical Health Care Institutions

As detailed in the Collection of Information section of this rule, we propose to reduce the discharge planning requirements for RNHCIs because RNHCIs do not provide medical treatment or services. Most patients are discharged to home or to another facility that also does not provide medical treatment or services. Although all patients must have a discharge planning evaluation, not all patients require a discharge plan. The discharge planning cost would be reduced by an estimated $27,013.16.

2. Effects on Ambulatory Surgical Centers and Hospital Outpatient/ Ambulatory Surgery Departments

As of May 2017 there were 5,557 Medicare-participating ASCs. We proposed to revise the ASC CfCs in order to reduce unnecessary duplications and streamline processes in order to reduce ASC compliance burden while maintaining minimum standards for patient safety and care. The specific savings for each proposed change are described later in this section of this proposed rule. At § 416.41(b)(3), we propose to remove the requirements related to transfer agreements and admitting privileges. This change would eliminate the administrative burden associated with preparing an agreement for signature and going through the hospital credentialing process in order to obtain admitting privileges. Currently, all Medicare-certified ASCs are meeting the transfer agreement or admitting privileges requirement with the exception of approximately twenty ASCs that have tenuous relationships with their local hospital. We estimate the ASCs that do have difficulty with meeting this requirement would appreciate the annual burden savings of 2 to 4 administrator hours spent on paperwork and documentation. For those already with the transfer agreements in place, there would not be any more follow-up burden related to renewals or updates to the documents. We estimate the savings at less than $10,000 overall and largely believe this change will not produce significant savings, however, it does affect twenty or more ASCs in the short term by removing the transfer agreement requirement. We welcome any feedback related to the time and effort for those ASCs that have secured an agreement, and if we have underestimated the savings of removing this transfer agreement in the future. As previously discussed, the enactment of EMTALA and its increasingly effective enforcement over time has rendered these transfer and admitting privileges obsolete and unnecessary. To put this point in perspective, emergencies or other unforeseen adverse events can arise in any ambulatory medical or dental setting, or in home settings. Over time, ''911'' emergency calls and direct ambulance responses have become standard operating procedures virtually nationwide, regardless of the place in which the problem arose. Under modern procedures, emergency responders (and patients themselves) take patients to hospital emergency rooms without regard to prior agreements between particular physicians and particular hospitals. Indeed, the most appropriate emergency treatment setting for a particular patient may not be one involving such an agreement even where the agreement exists. Of course, nothing prevents particular arrangements where a hospital and ASC agree that this is beneficial for a particular type of surgery or patient condition and where patient transport can be appropriately arranged to reflect this. Accordingly, we estimate that there will be no consequential adverse health effects of this proposed change, and therefore estimate no medical costs.

There will be competitive benefits in those places where an ASC will now be allowed to operate and provide care at reduced cost compared to inpatient treatment. Nonetheless, we believe that the number of affected areas and facilities are few, and that annual benefits are unlikely to reach the

million dollar range. We welcome comments on these effects and on the preceding analysis of health effects.

At § 416.52 we propose to replace the requirement that every patient must have a comprehensive H&P within 30 days prior to surgery in an ASC with a requirement that allows the operating physician and ASC to determine which patients would require more extensive testing and assessment prior to surgery. We believe that this change would reduce patient and provider burden in a multitude of ways that includes the community-based physician, the ASC, and the patient. We believe that in almost all situations ASCs can reasonably rely on existing H&P results that are more than 30 days old and then are updated by patient responses on the day of surgery, but we cannot forecast with any precision what medical specialty societies, ASC governing bodies, hospital governing bodies, or accreditation bodies will decide to do in replacing the current requirement. Therefore, we do not forecast specific cost savings at this time, and solicit public comments to help us with our estimate in the final rule.

For ASCs, we believe this change would reduce administrative burden by decreasing the amount of time that ASC personnel spend following up on patient visits to obtain the necessary H&P information and that it will provide for an increase in scheduling flexibility for the facility. We believe these changes may have the effect of improving patient satisfaction and increasing positive patient referrals for the ASC.

For community-based healthcare providers, to include primary care providers, we believe this change would reduce unnecessary examinations that are required to be performed and reduce administrative paperwork burden associated with providing ASCs with the necessary H&P documentation and additional testing requirements. This change may potentially provide an opportunity for increased access to community-based providers because of available appointments that are not being filled by unnecessary patient appointments for H&P requirements for surgery in an ASC. Those vacant appointments may also generate more revenue.

For patients, we believe this change would reduce the time spent to prepare for surgery (time in community-based physician office, travel time and costs, time missed from the work place and lost productivity) and the cost associated with co-pays and other healthcare cost sharing requirements.

Finally, we believe this change would reduce expenses for healthcare insurers to include Medicare, Medicaid, and private healthcare insurance companies. This change would reduce costs associated with reduced pre-operative exams, laboratory testing, chest radiographs, and echocardiograms.

It is difficult to estimate the savings from this change, because they depend on a number of factors previously described, and additional factors for which we do not have precise measures, such as the number of patients (both Medicare and non-Medicare) who received two or more ASC services within the 30-day window allowed for one physical examination. This is a common occurrence because, for example, patients often receive cataract surgery on one eye and then, a week later, on the other eye. Furthermore, there are an immense number of different outpatient surgical services. At present, for example, there are about 137 services that account for about 90 percent of ASC volume, and these services are highly diverse, as shown in Table 13.

TABLE 13—TWENTY MOST FREQUENT ASC SERVICES IN 2015

Surgical service	Rank	Percent of volume
Cataract surgery w/IOL insert	1	18.60
Upper GI endoscopy, biopsy	2	8.2
Colonoscopy and biopsy	3	6.8
Lesion removal colonoscopy (snare technique)	4	5.6
Inject foramen epidural: Lumbar, sacral	7	4.8
After cataract laser surgery	6	4.4
Injection spine: Lumbar, sacral (caudal)	8	3.3
Inject paravertebral: Lumbar, sacral	9	3.1
Diagnostic colonoscopy	5	2.3
Colorectal screen, high-risk individual	10	2.0
Colorectal screen, not high-risk individual	12	1.9
Cataract surgery, complex	11	1.6
Injection procedure for sacroiliac joint, anesthetic	19	1.3
Cystoscopy	15	1.2
Upper GI endoscopy, diagnosis	13	1.0
Inject spine, cervical or thoracic	17	1.0
Revision of upper eyelid	16	0.9
Lesion removal colonoscopy (hot biopsy forceps)	14	0.8
Upper GI endoscopy, insertion of guide wire	18	0.8
Carpal tunnel surgery	20	0.7
Total	.....	70.4

Source: MEDPAC. Ambulatory surgical center services. 2017, p. 140.

In total, ASCs provided about 6.4 million services in 2015 (MEDPAC. Ambulatory surgical centers services, 2017, p. 139). If we assume that 25 percent of these had two or more services within the 30-day ''window'' allowed in the current rule, then another H&P with its associated battery of tests were required for each of the remaining 4.8 million individuals. Assuming that 5 percent of these would otherwise have already had an overall H&P and associated tests within 30 days of the surgery, 4.56 million persons would then require a new H&P and tests before surgery under the current requirements. In the great majority of cases involving eye or eyelid surgery of one kind or another, the ophthalmology examination preceding the ASC surgery would not have involved a

comprehensive H&P or battery of tests, and a similar situation would be involved for most other surgeries preceded by specialist rather than primary care visits.

Although we are unable to estimate the likely number of cases, one way to estimate the costs of these examinations and tests would be as follows. First, the H&P itself would cost approximately $100 (the exact amount depending on diagnostic details, and not necessarily corresponding to any particular payment schedule). The battery of tests would cost approximately $100, assuming both urine and blood testing, and, in some cases, an electrocardiogram, but only half of physical examinations (for example, few or no ophthalmologist exams) would include such tests. The travel of the patient to and from the physician office to obtain the examination and tests would on average require 1 hour, which when valued at the average wage rate in the economy of $24 (increased by 50 percent to include fringe benefits but not overhead) would cost about $36. In addition, ASCs incur substantial costs for the time and trouble needed to contact physician offices and arrange for the results to be delivered. The physician offices themselves would be put through the trouble of transferring those medical records. Assuming average time spent (the median would be less but a small number of difficult cases would bring the average well above the median) would reach 10 minutes, and the use of a general office clerk at $32 an hour, the cost per patient would average $5 per patient. A further cost arises because in many cases the examination and test results simply cannot be obtained timely, and a scheduled surgery has to be postponed. Assuming that in such cases a half hour of surgeon time (at $243 an hour) and a half hour of registered nurse (RN) time (at $69 an hour) is wasted, and that clerical time ($32 an hour) to reschedule averages 10 minutes, the average cost per postponement would be $161. (In some of these cases patient time would be wasted, as well as the time of family members accompanying the patient—we have not estimated these costs.)

Aggregating these calculations, one estimate of the annual costs of the current regulatory requirement, as shown in Table 14, could be as much as $972 million for ASCs and a similar amount for hospital outpatient surgery. For many and perhaps most cases, however, either the surgeon or the facility would decide that H&P information is needed for particular patients or particular procedures whether or not this regulatory requirement existed. Of course, it is unlikely that in such cases a strict 30-day window would be insisted on. Assuming that such examination and testing information would continue to be needed for 10 percent of all patients, and that in half of these cases the information would require a new examination and tests within a 30-day window, the net costs of the current regulatory requirement would be 5 percent less than the preceding calculations. Supposing that such examination and testing information would still be required for 50 percent of all patients, the costs of the current requirement and hence the potential savings from its reform would fall much further. Absent more specific information, the estimates of potential costs and savings in Table 14 are suggestive but not robust until or unless improved through public comment and additional information. In our summary estimates, we have assumed a range of savings from zero to 50 percent, with a midpoint of 25 percent.

As support for the 50 percent upper bound, we note that Chen CL, Lin GA, Bardach NS, Clay TH, Boscardin WJ, Gelb AW, Maze M, Gropper MA and Dudley RA, Preoperative Medical Testing in Medicare Patients Undergoing Cataract Surgery, New England Journal of Medicine 372:1530–1538, April 16, 2015, find that approximately 53 percent of Medicare cataract patients undergo pre-operative testing, none of which is mandated by CMS regulation. If these patients' physicians are cautious enough to currently pursue more preoperative activity (testing, H&P, etc.) than what is required, or state or hospital rules are driving physician behavior beyond what Medicare necessitates, then there is little reason to believe that that behavior will change with the finalization of this rule. Given that other procedures tend to be more invasive than cataract surgery, pre-operative caution on the part of physicians is likely to be even greater in the non-cataract context. Indeed, Benarroch-Gampel J, Sheffield KM, Duncan CB, Brown KM, Han Y, Townsend CM and Riall TS, Preoperative Laboratory Testing in Patients Undergoing Elective, Low-Risk Ambulatory Surgery, Annals of Surgery 256(3):518–528, September 2012, and Fischer JP, Shang EK, Nelson JA, Wu LC, Serletti JM and Kovach SJ, Patterns of Preoperative Laboratory Testing in Patients Undergoing Plastic Surgery Procedures, Aesthetic Surgery Journal 1(1):133–141, January 2014, find that almost two-thirds of hernia procedures are preceded by testing, as are 62 percent of ambulatory plastic surgeries. This leaves an upper bound of 33 to 38 percent of non-cataract outpatient surgery H&P costs that could reasonably be expected to be avoided as a result of this rulemaking. In order to more successfully tailor the upper bound of potential cost savings to H&P activity—rather than just extrapolating from testing behavior—we request comment on the possibility of building on Chen et al.'s data and methodology to estimate the increased frequency of within-30-day office visits (presumed to be H&P) when ophthalmologist visits are at least 31 days prior to surgery relative to when ophthalmologist visits are no more than 30 days prior.

As noted in the medical literature previously discussed, Chung F, Yuan H, Yin L, Vairavanathan S, and Wong DT. Elimination of preoperative testing in ambulatory surgery. Anesth Analg. 2009 Feb, 108(s):467–75, there are no known consequential medical benefits from the testing often performed in association with the current regulatory requirements. This study covered hernia patients but similar results have been found in studies of cataract surgery. Accordingly, eliminating the testing could in theory produce very substantial annual ASC cost savings with no offsetting medical cost increases or harm to patients. H&P itself, however, is distinct from testing, and literature indicating that testing is wasteful does not necessarily speak to the importance of H&P. Therefore, if H&P is avoided, rather than more thoroughly integrated into same-day presurgical assessments, there could be adverse consequences to patients; these impacts have not been quantified.

As discussed in ''Provisions of the Proposed Regulations,'' section II.D. 2. of this proposed rule, there is a similar regulatory requirement for hospital outpatient surgery. Based on the substantial similarity between these two service settings, we also propose to eliminate these requirements for such surgery. Although we do not have detailed data for hospital outpatient surgery, it is widely agree to be roughly equal in size and composition to ASC surgery, though spending is higher because a higher payment schedule is used by some insurers, including Medicare, for most hospital outpatient surgery. Regardless, estimates should be based on economic costs, not any particular payment schedules. Accordingly, potential total annual savings, and hence benefits, for both settings taken together could be as much as $1.7 billion. This would depend on whether hospital-based outpatient

surgery decisions parallel those of independent ASCs.

If, after ASCs and hospitals make policy decisions on which types of outpatient/ambulatory surgery patients would require a comprehensive H&P, it is found that only 50 percent of current costs were continued, potential total annual savings, and hence benefits, for both settings taken together could be as much as $908 million, assuming that hospital-based outpatient surgery H&P policy decisions parallel those of independent ASCs. Alternatively, if 75 percent of current costs were continued, potential savings would be only about $454 million annually. While the literature shows that we can be reasonably certain that for some procedures, such as cataract surgery, few or possibly even no costs would be self-imposed, there may be other procedures where ensuing policy decisions would retain all current history and physical requirements, though likely removing the strict 30-day rule. Because of the proposed requirements, and other uncertainties, the potential savings from lifting the current requirements encompass at least this broad range and quite possibly more. Because there is great uncertainty in these estimates we have decided not to present a predetermined figure in this proposed rule. Instead, we are requesting public comments on all the parameters of our estimates to inform the estimates we will make in the final rule. We welcome information on likely decisions in both ASC and hospital outpatient settings, and if possible for the most common procedures shown in Table 13 and for the likelihood and cost saving effects for procedure and patient categories where the facility chooses to retain an external H&P requirement, but extends the time window to a year or some other period that is far longer than 30 days.

TABLE 14—CURRENT COSTS AND POTENTIAL ANNUAL SAVINGS FROM CREATING AND OBTAINING EXAMINATION AND TEST RESULTS

Type of cost	Unit cost	Number (M)	Current total cost ($M)	Twenty-five percent retained ($M)	Fifty percent retained ($M)	Seventy-five percent retained ($M)
Physical Examinations	$100	4.56	$456	$114	$228	$342
Test Batteries	100	2.28	228	57	114	171
Patient Travel Cost	36	4.56	164	41	82	123
Administrative Cost to ASC	5	4.56	23	6	11	17
Surgery Cancellations *	161	0.228	37	9	18	28
Total Cost, ASCs	.....	.....	908	227	454	681
Total Cost, Hospital Outpatient **	.....	.....	908	227	454	681
Total Cost	.....	.....	1,815	454	908	1,362
Total Savings	.....	.....	.....	1,362	908	454

* Based on information from a major ambulatory surgery facility, this estimate assumes that 5 percent of scheduled cataract operations are cancelled at the last minute since the required H&P information has not arrived from the physician office where the examination was performed and the tests ordered or performed. Staff salaries must still be paid. Our estimates assume one half hour of surgeon time wasted (at $243 an hour), one half hour of RN time wasted (at $69 an hour), and ten minutes of clerical time (at $32 an hour) to reschedule.

** Hospital outpatient savings assumed to be equal to ASC savings.

We assume that the one-time costs of developing such policies for hospital outpatient surgery in 5,031 Medicare-participating hospitals would be the same in the aggregate, though the mix of personnel used would be somewhat different and the cost at free-standing hospitals would likely be several times higher (for example, for involvement of the governing body and legal review). About 3,200 of these hospitals are in multi-hospital systems that would, however, reap economies of scale, and about 574 are psychiatric hospitals that we assume rarely perform surgery. In total, we estimate that, first year savings for both types of facilities would be $38 million less, regardless of the replacement rules that each facility imposed on itself.

There are possible alternatives, including limiting the regulatory reform to the lowest risk procedures, which would probably mean almost all procedures, excluding certain procedures from the regulatory reform, exempting ASCs, but not hospital outpatient departments, changing the 30-day requirement to something much longer in duration such as 6 months or a year, and likely others. Absent contrary evidence, however, we believe that relying on physician and facility judgment maximizes benefits and presents no consequential costs.

We welcome comments on these estimates and on both the proposal and any alternatives, and particularly welcome any evidence-based information that would inform both our ability to provide cost savings estimates and a policy choice between either the proposed reform or an alternative.

3. Effects on Hospices

As of May 2017 there are 4,602 Medicare participating hospices. We proposed to revise the hospice CoPs in order to reduce unnecessary duplications and streamline processes in order to reduce hospice compliance burden while maintaining minimum standards for patient safety and care.

At § 418.76(a) we propose to defer to State training and competency requirements, where they exist, for hospice aides. Deferring to state requirements would streamline the hiring process because hospices would not have to verify that a job candidate's qualifications meet or exceed the Federal standard in addition to verifying that the candidate meets State requirements.

According to the BLS, 408,920 aides are currently employed in ''home care''. The term ''home care'' encompasses both home health agency and hospice employers. There are 12,624 HHAs and 4,602 hospices, meaning that hospices represent 27 percent of the ''home care'' employer market. Thus, we conclude that hospices employ 110,408 aides (27 percent of all aide positions in ''home care''). Based on an informal survey conducted by the largest hospice industry association, 76 percent of

States have their own training and competency requirements, accounting for approximately 83,910 aide positions. Hospices in these states would benefit from the proposed change because they would be permitted to rely on the completion of state mandated training and competency programs to assure that a candidate is qualified for employment, and would no longer have to take the additional step of verifying that each potential job candidate also meet the Federal requirements. We assume a 25 percent turnover rate based on discussions with industry experts, or 20,978 aide job listings per year. Based on an assumed 20 candidates that would require the qualifications verification per job listing, we estimate that hospices must verify the training and competency program content and format for 419,560 candidates per year. We assume that it would take 10 minutes per candidate to verify compliance with the Federal requirements, for a total of 69,927 hours per year nationwide. At a cost of $32 per hour for a general office clerk to perform this check, we estimate that hospices will save $2,237,664 annually.

At § 418.106(a) we propose to delete the requirement that a hospice must ensure that the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs. Not requiring the specific pharmacy advisement function would allow for more streamlined interdisciplinary group meetings. We assume that 25 percent of hospices currently use their own staff (employee or contract) for this function, and that this staff member is typically the nurse member of the interdisciplinary group. The nurse member of the interdisciplinary group is also required by § 418.56(a); therefore we believe that removing this requirement will not result in removing the expertise from the group. Rather, we believe that removing this requirement will remove the formulaic approach to interdisciplinary discussions whereby the group allots time in each meeting specifically for this discussion in order to assure regulatory compliance. In the absence of regulation, the interdisciplinary group would have the authority to decide whether the discussion is pertinent for a given patient and the information can be woven into the discussion at large. This approach has the potential to reduce the overall group discussion time, particularly for the 3 members of the interdisciplinary group that are not charged with being the pharmacology expert. Based on 1.6 million hospice patients and an assumed 3 interdisciplinary group meetings per patient, there are a total of 4,800,000 interdisciplinary group meetings per year. We assume that each interdisciplinary group meeting includes 2 minutes of time specifically related to discussing the results of the pharmacy advisement service for purposes of complying with the regulation, or 160,000 hours per year nationwide. At a cost of $299 per hour ($198 physician + $53 social worker + $48 pastoral counselor), we estimate that removing this requirement would save $47,840,000 annually.

Additionally, we believe that this change would reduce the specialist nursing time spent specifically on advisement services. We believe that moving away from a regulatory compliance ''check box'' approach would allow the specialist nurse to incorporate medication management more seamlessly into regular clinical practice. The 2008 Hospice CoP final rule (73 FR 32088) estimated a 1 hour burden per patient for expert pharmacy services (30 minute initial advisement per patient + 2 15 minute update advisements) for a total cost of $69 per patient for all advisement services (updated to 2017 dollars). We estimate that this proposed change would reduce that time by 50 percent, to 30 minutes per patient, resulting in a $35 per patient savings. Based on the assumption that 25 percent of hospices use their own employee to perform this function, we estimate that this reduction would occur for 400,000 patients nationwide (25 percent of 1.6 million hospice patients), for a total annual savings of $14,000,000.

Together with the previously stated estimate, total savings would be $47,840,000 + $14 million = $61,840,000 annually.

We propose to revise the requirement at § 418.106(d) to allow hospices to provide information regarding safe medication use, storage, and disposal in a more understandable manner. Under the current requirements, hospices are required to provide patients and families with a copy of the hospice's policies and procedures, which are not written in layperson terms. The proposed change would alleviate the burden associated with addressing the confusion created by the policies and procedures document. Following the initial cost of $483,210 (described in section III.E. of this rule) for developing new, more easily understandable materials for patient education, we believe that hospices would realize a savings of 10 minutes per patient because it would require less hospice staff time to explain the more understandable material. Based on an assumed 10 minutes of saved nursing time per patient, and 1.6 million patients, hospices would save 266,667 hours. At a cost of $69 per hour, the total savings would be $18,400,023.

First year: $18,400,023 savings − $483,210 initial year cost = $17,916,813 net savings.

Annually thereafter: $18,400,023 savings.

At § 418.112(f) we propose to allow hospices and long term care facilities the additional flexibility to negotiate the format and schedule for orienting long term care facility staff regarding certain hospice-specific information. We believe that this would allow for innovation and streamlining, and reduce hospice compliance costs related to this requirement by 20 percent. For purposes of our analysis only, we assume that a typical hospice conducts 6 orientation sessions per year, and that each orientation requires 2 hours of time from a hospice nurse. At a cost of $69 per hour, a typical hospice would spend $828 each year to orient long term care facility staff. Assuming a 20 percent reduction in burden that can be achieved through innovation and streamlining, a typical hospice would save $166 a year, or $763,932 savings annually for all 4,602 hospices.

Taken together, these proposed reforms would generate annual savings of approximately $82.8 million ($47.8 million for reduced interdisciplinary group meeting time + $14 million for reduced specialty nursing time + $18 million for streamlined controlled drug education practices + $2.2 million for streamlined hospice aide qualification requirements + $0.8 million for streamlined facility staff orientation). We welcome public comment regarding these burden estimates, and additional regulatory reforms to reduce the burden of the hospice CoPs.

4. Effects on Hospitals

As of May 2017, there were 5,031 Medicare participating hospitals. We propose to revise the hospital CoPs in order to simplify some requirements and streamline processes in order to reduce burden associated with hospital compliance with the Medicare CoPs while maintaining minimum health and safety standards. The specific savings for each proposed change are described below.

At § 482.21, we propose to allow for multi-hospital systems using a system governing body, as allowed under the CoPs, and that is legally responsible for two or more separately certified member hospitals, to have a unified QAPI program for the member hospitals subject to the system governing body. This will afford hospitals flexibility and the ability to gain efficiencies and achieve significant progress in quality by sharing best practices among all hospitals subject to the system governing body. This would be similar to current allowances for system governing bodies and unified medical staffs.

While there are no current requirements that explicitly prohibit the sharing of best practices across a system, the current requirements for each hospital to have its own separate and distinct QAPI program and Infection Control program certainly have inhibited and stifled sharing of best practices and innovations among individual hospitals within a system as we point out in the preamble to this proposed rule, and which we support with our reference to the Health Research and Educational Trust, in partnership with the American Hospital Association March 2010 publication entitled, ''A Guide to Achieving High Performance in Multi-Hospital Health Systems.'' This publication, along with positive public comments regarding unified medical staffs that we discussed in the May 2014 final rule and to which we refer in this proposed rule, clearly point to multi-hospitals more efficiently and effectively collecting, disseminating, and sharing innovations, solutions, and best practices for patient care to each of its member hospitals through these unified patient care programs.

Approximately 3,200 of the 5,031 Medicare-participating hospitals participate in a hospital system (American Hospital Association (AHA), *Fast Facts 2017* (*https://www.aha.org/system/files/2018-01/fast-facts-us-hospitals-2017_0.pdf*)). According to the 2017 AHA Guide, there are 424 multi-hospital systems. The current regulatory burden for compliance with the QAPI program requirement is approximately $10,000 annually per hospital or $50.3 million annually for all 5,031 hospitals. If we were to allow a unified QAPI program for multi-hospital systems, this would remove 3,200 hospitals from the total 5,031 (replaced by the 424 multi-hospital systems) for a total of 2,255 hospitals/multi-hospital systems that would still need to comply. The new regulatory burden would be a total of approximately $22.6 million annually (2,255 × $10,000), for an annual total savings of approximately $28 million. We welcome comments on the quantitative and non-quantitative portions of the preceding discussion and seek any empirical evidence that would improve the accuracy and thoroughness of the relevant benefits estimation.

We propose to remove the requirement for hospitals at § 482.22(d), which states that a hospital's medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. Because this requirement is redundant and more detailed, specific requirements regarding medical-legal investigative autopsies are required by individual state law, we do not anticipate that hospitals would accrue additional savings from this change. The benefit to hospitals from eliminating this requirement is realized through a reduction in burden from no longer having to comply with two similar requirements of the Federal government and the State government. Hospitals would instead be required to follow the more detailed, specific regulations of the state in which they are located.

At § 482.42, we propose to allow for multi-hospital systems using a system governing body as currently allowed under the CoPs, and that is legally responsible for two or more separately certified member hospitals, to have a unified infection control program for those member hospitals subject to the system governing body. This would allow hospitals flexibility and the ability to gain efficiencies and achieve significant progress in infection prevention and control. This would also be similar to current allowances for system governing bodies and unified medical staffs.

The current regulatory burden for compliance with the Infection Control program requirement is approximately $191 million annually for all hospitals or $38,000 per hospital. If we were to allow a unified Infection Control program for multi-hospital systems, this would remove 3,200 hospitals from the total 5,031 (replaced by the 424 multi-hospital systems) for a total of 2,255 hospitals/multi-hospital systems that would still need to comply. The new regulatory burden would be a total of approximately $86 million annually (2,255 × $38,000), for an annual total savings of approximately $105 million. We welcome comments on the quantitative and non-quantitative portions of the preceding discussion and seek any empirical evidence that would improve the accuracy and thoroughness of the relevant benefits estimation. At §§ 482.58(b)(1) and 485.645(d)(1) (cross-referenced long-term care requirement at § 483.10(f)(9)) we propose to remove the requirement for hospital and CAH swing-bed providers to provide the right for patients to choose to or refuse to perform services for the facility and if they so choose, (a) document in the resident's plan of care, (b) noting whether the services are voluntary or paid and (c) provide wages for the work being performed given the location quality, and quantity of work requiring comparable skills. We discuss the economic impact for this provision in the ICR section of this rule, which is estimated to be $32 million.

At § 482.58(b)(4) (and § 485.645(d)(4)) (cross-referenced long-term care requirement at § 483.24(c)), we propose to remove the requirement for hospital and CAH swing-bed providers to provide an ongoing activity program that is directed by a qualified therapeutic recreation specialist or an activities professional who meets certain requirements as listed at § 483.24(c)(2). We discuss the economic impact for this provision in the ICR section of this rule, which is estimated to be $81 million.

We propose to remove the requirement at §§ 482.58(b)(5) and 485.645(d)(5) (cross-referenced long-term care requirement at § 483.70(p)) for hospital and CAH swing-bed providers to employ a qualified social worker on a full-time basis if the facility has more than 120 beds. Given that this provision is not applicable to either provider type due to the regulatory requirements for each, it does not impose a burden upon hospitals and as such, its removal would not result in a savings of burden hours or dollars.

At §§ 482.58(b)(8) and 485.645(d)(8) (cross-referenced long-term care requirement at § 483.55(a)(1)) we propose to remove the requirement for hospital and CAH swing-bed providers to assist in obtaining routine and 24-hour emergency dental care to its residents. We discuss the economic impact for this provision in the ICR section of this rule, which is estimated to be $2.9 million for all hospital and CAH swing-bed providers.

At § 482.61(d), we propose to allow non-physician practitioners to document progress notes in accordance with State laws and scope of practice requirements. We discuss the economic impact for this provision in the ICR section, which is estimated at $54.7 million in savings for psychiatric hospitals.

5. Effects on Transplant Programs and Patients

There are approximately 750 Medicare approved transplant programs in the United States, of which 250 are kidney transplant programs. All Medicare approved transplant programs must be a part of a Medicare approved hospital, and many hospitals have several types of organ programs. Oversight of these programs occurs in two major ways: By the Organ Procurement and Transplantation Network (OPTN), which is a non-profit membership-based organization operated under a Federal contract administered by the Health Resources and Services Administration (HRSA), and by CMS under the CoPs. The current and long-term OPTN contractor is the United Network for Organ Sharing (UNOS), which performs many transplantation functions, including matching donated organs to waiting lists of patients who have failing organs, and reviewing the performance of transplant centers on a variety of criteria, including patient and organ survival. There is a third mechanism encouraging better transplant program performance, the SRTR (accessed at *https://www.srtr.org*). The SRTR, also operated under a HRSA contract, provides detailed data on the performance of all transplant programs, and allows the OPTN, individual transplant programs, and patients themselves to compare results on such vital metrics as patient survival rates after transplant.

For patients with most types of organ failure, a transplant is the only option for long-term survival. In the case of kidney failure, however, kidney dialysis is a viable medium-term and sometimes long-term option for most patients. On average these patients can survive a dozen or more years on dialysis; however, without a transplant, they suffer increasingly high morbidity and mortality rates. We provide Medicare coverage for such patients through the ESRD program. Under the ESRD program, patients receive dialysis treatment, usually three times a week, through machines that cleanse their blood in much the same way as healthy kidneys would do. Since its inception in 1973, more than one million patients have received treatment under this program. Kidney failure patients are unique in another way: Unlike most other organs, with the partial exception of some liver donations, it is possible for living individuals to donate ''live'' kidneys, whether the living donor is a relative or an unrelated altruistic donor. In the case of ESRD patients, the Medicare ESRD program serves almost all kidney failure patients, regardless of age, and these patients receive costly dialysis for a prolonged period of time. As is the case for all CoPs, our regulations for Medicare-approved organ transplant programs have the potential to protect all patients, not just Medicare beneficiaries.

As discussed earlier in this preamble, we have long regulated transplant programs, but put in place additional CoPs in the March 2007 final rule (72 FR 15198) in an effort to increase the quality of care by specifying minimal health and safety standards. In addition, outcome metrics (1 year graft and patient survival) were included in the regulation and mirrored the OPTN outcomes metrics as calculated by the SRTR. Over time, increased emphasis on organ and patient survival rates, as key metrics of transplant performance, created incentives for transplant programs to select organs most likely to survive after transplant without rejection, and to select recipients most likely to survive after the transplant. In particular, due to the increasing patient and organ survival rates over time, the 2007 standards have become increasingly stringent over time as an artifact of the performance calculation method established in the 2007 rule, an outcome that was never intended by CMS. In addition, the 2007 rule created performance standards that focused only on organ and patient survival rates for those who received a transplant, not on survival rates of patients awaiting transplant. We refer readers to a discussion of this problem in the following CMS compliance Guidelines that could only partially lighten this unintended regulatory burden at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-24.pdf.*

There is extensive literature on these incentives and other phenomena in transplant medicine that strongly suggests some unintended consequences on organ utilization (decreased use of ''marginal'' organs in their patients) and de-selection of some patients who are slightly less likely to survive for an extended period post-transplant. These unintended consequences have been anecdotal and measuring the extent to which they have occurred is difficult. In addition to the studies previously cited in the preamble (Adler et al., Schold et al., Dolgin et al., Stewart et al., Husain et al.), other studies on this issue include Kasiske B, Salkowski N, Wey A, Israni A, and Snyder J, ''Potential Implications of Recent and Proposed Changes in the Regulatory Oversight of Solid Organ Transplantation in the United States,'' *American Journal of Transplantation,* Volume 16, Issue 12, December 2016, pages 3371–3377; Howard R, Cornell D, and Schold J, ''CMS Oversight, OPOs and transplant centers and the law of unintended consequences, *Clinical Transplantation,* Volume 23, Issue 6, November/December 2009, pages 778–783; and Abecassis M, Burke R, Klintmaim G, Matas A, Merion R, Millman D, Olhoff K, and Roberts J, ''American Society of Transplant Surgeons Transplant Center Outcome Requirements—A Threat to Innovation,'' *American Journal of Transplantation,* Volume 9, Issue 6, June 2009, pages 1279–1286; and Schold J, Miller C, Mitchell H, Buccine L, Flechner S, Goldfarb D, Poggio E, and Andreoni K, ''Evaluation of Flagging Criteria of United States Kidney Transplant Performance: How to Best Define Outliers,'' *Transplantation,* June 2017, Volume 101, Issue 6, pages 1373–1380. These studies regarding the reduced number of transplants that would otherwise have occurred, yielded several relevant facts. The number of deceased donor organs that are discarded has been increasing over time and for kidneys, is above 20 percent. For example, about 33 percent of kidneys recovered from donors age 50 to 64 are discarded, as are about 62 percent of kidneys recovered from donors age 65 or older (Hart A. et al., OPTN/SRTR 2015 ''Annual Data Report: Kidney.'' Accessed at *http://onlinelibrary.wiley.com/doi/10.1111/ajt.14124/full*). Officials of the UNOS have stated at public meetings that in their judgment up to 1,000 kidneys of the approximately 3,000 that are discarded each year are of good enough quality to be transplanted successfully. The number of organ transplantations reached record highs in 2016 (33,500), about 20 percent more than 5 years earlier, due mainly to increased donation rates (OPTN, ''United States organ transplants and deceased donors set new records in 2016.'' Accessed at *https://optn.transplant.hrsa.gov/news/us-organ-transplants-and-deceased-donors-set-new-records-in-2016/*).

For purposes of this analysis, one approach to estimating effects is to isolate the number of kidneys (and other organs) that have been discarded as a result of the March 2007 rule; indeed, a reasonable assumption would be that this proposed rule's rescission of the 2007 requirements would have an equal and opposite effect. A slide presentation by UNOS researcher Darren Stewart (2017; accessed at *https://www.myast.org/sites/default/files/ceot2017/AST%20CEOT%2001%20*

Stewart%20-%20No%20Organ%20Left%20Behind%20-%20S3.pdf), presents an estimate that about 1,110 of about 2,759 kidneys discarded in 2012 were of transplant quality and that between 500 and 1,000 of these could have been used in transplants (the most recent discard numbers, for 2016, are about 20 percent higher than in 2012 and one-third higher than in 2007). This presentation cites the study previously discussed in this preamble (Stewart et al. (2017)), that shows kidney discard rates rising from between 5 and 7 percent in the late 1980s to 19.2 percent in 2015. Notably, the discard rate had already reached approximately 18 percent by 2007, making the rate of increase much lower after the March 2007 rule was implemented than it had been in the previous two decades. Although this contrary evidence is far from definitive, it suggests that the effect of the March 2007 rule was too small to be observable in the kidney discard data.

Unfortunately, these and other studies have had to deal with other trends during the last two decades that greatly complicate measuring the independent effect of the 2007 rule. These include the increasing age of the donor pool and the attendant decline in some dimensions of organ quality, and the opposite effects of improved techniques for maintaining organ quality between the time of donation and the time of transplantion. As a result, the published studies using data on organ discards have had to use complicated multivariate statistical procedures in attempting to estimate the effects of the 2007 rule, and invariably conclude that their findings are subject to considerable uncertainty.

The preceding analysis focuses on discard rates as a tool that transplant programs can use to reduce risk of lower patient or organ survival rates, and hence risk of closure under the 2007 rule. A second tool that a transplant program can use to reduce its risk of lower overall patient survival rates is to remove patients who are slightly less likely to survive from its waiting list, most commonly by making a judgmental decision that the patient is ''too sick for transplantation.'' Programs that are on the margin of receiving regulatory sanctions, or that have received such sanctions already, are particularly likely to exercise such judgments to reduce regulatory risk. Several studies have estimated specific numbers of transplant reductions due to the 2007 rule by comparing the number of patients removed from the waiting list at programs that have received regulatory sanctions to those that have not. To provide a baseline, these studies make the conservative assumption that those programs with zero sanctions have not removed any patients from their transplant waiting list in order to avoid sanctions. For kidneys, one study estimated that in the seven year period from 2007 to 2014, the lower performing programs removed from waiting lists over 2500 patients more than would have been expected absent sanctions, an average of over 350 per year (J.D. Schold et al., ''Association of Candidate Removals From the Kidney Transplant Waiting List and Center Performance Oversight,'' American Journal of Transplantation 2016, 1276–1284). The implications, for the present time, of wait list changes initiated in 2007 is unclear. Increased mortality in 2007 among the very sick patients who were dropped from the wait list would have freed up organs for 2007's moderately sick patients; these patients otherwise would have declined in health so as to be the very sick population in 2008. Thus the absolute level of health in 2008 would have been relatively good, in which case the phenomenon of patients being dropped from the wait list might not have perpetuated into the future, leaving little or no scope for benefits to be achieved now as a result of the proposed CoP revision. (We note that one year, from 2007 to 2008, may be an exaggeration as to the short-term nature of this wait list-related effect, but a somewhat longer tapering period could still have reached completion now, more than a decade after the implementation of the 2007 CoP, thus leaving little scope for benefits.) On the other hand, if the sickest patients in 2008 were dropped based on their relative health levels—in spite of their improved absolute health relative to the sickest patients in 2007—there would be potential wait list-related benefits from revising this CoP at the present time. The benefits of shifting transplants to the sickest patients from relatively less sick patients have not been quantified, but because the harm to the less sick patients would need to be netted off the benefit to the sickest patients, the per-transplant magnitude would be much lower than the per-transplant benefits of avoided organ discards.

Another quantitative study of kidney transplant effects used a similar methodology and estimated that as a result of the 2007 rule, in 2011 sanctioned programs performed 766 fewer kidney transplants than would otherwise have been the case (Sarah L. White et al., ''Patient Selection and Volume in the Era Surrounding Implementation of Medicare Conditions of Participation for Transplant Programs,'' Health Services Research, April 2015, 330–350). White et al.'s finding of reduced transplant volumes at particular kidney transplant centers does not necessarily indicate decreased transplant volumes overall, with the authors stating that their aggregate results ''do not indicate that the introduction of the [2007] CoPs has systematically reduced opportunities for marginal candidates or that there has been a systematic shift away from utilization of higher risk deceased donor kidneys.'' In other words, regulatory sanctions could have triggered behavioral responses by some patients, some transplant surgeons, or some health insurance plans to shift patients away from these centers (many insurers restrict coverage through ''centers of excellence'' programs). Schold et al. (2013) find additional support for this phenomenon, describing their empirical result as follows: ''Among 203 [adult kidney transplant] centers, 46 (23%) were low performing (LP) . . . Among LP centers, there was a mean decline in transplant volume of 22.4 cases compared to a mean increase of 7.8 transplants among other centers.'' The estimated decrease per low-performing transplant center is roughly three times the increase per other center, but there are also roughly three times as many other centers as low-performing centers; as such, the most straightforward interpretation of this paper is that the same number of transplants is being concentrated in a smaller number of transplant centers. This outcome could still have real impacts, such as changes in travel time for patients, but although these impacts are valid for inclusion in a regulatory impact assessment, they would be much smaller in magnitude than the longevity benefits emphasized elsewhere in this analysis.

A feature common to most of these studies that is that they use data that are already several years old when the study is published, both because of the usual publishing lag and because performance data such as one-year survival rates necessarily make transplant program results less timely. None of these studies covers the last two or three years of transplant program performance. As a result, none of these studies has been able to use actual data to assess the effects of the May 13, 2016 CMS changes that slightly reduced the performance level for finding a ''condition-level'' violation that threaten's program closure. For recent reviews of potential effects of those changes see B.L. Kasiske et al., ''Potential Implications of Recent and

Proposed Changes in the Regulatory Oversight of Solid Organ Transplantation in the United States,'' Am J Transplant, December 2016, 16(12), 3371–3377, and Colleen Jay and Jesse Schold, ''Measuring transplant center performance: The goals are not controversial but the methods and consequences can be,'' Curr Transplant Rep, March 2017, 4(1), 52–58. Using past data to measure potential effects, these studies predict little or no positive effect from the revised standards (which both studies conclude will still mis-identify lower performing programs), but cannot evaluate actual effects because post-issuance evidence is not yet available. This may not be relevant policy-wise, since we propose to eliminate those standards, but it is a key question for estimating the remaining scope (if any) of CoP-associated unnecessary organ discards, and it does flag the pervasive problem of timeliness of data and timeliness of study findings.

There are several studies that make similar estimates for liver transplant programs (for example, L.D. Buccini, et al., ''Association Between Liver Transplant Center Performance Evaluations and Transplant Volume,'' American Journal of Transplantation 2014, 2097–2105). This study found a large difference in transplant volume between programs rated as lower performing by the SRTR (average decrease of 39.9 transplants from 2007 to 2012) and those not receiving adverse SRTR ratings (average increase of 9.3 transplants over the same period). The 27 lower performing centers thus reduced their total number of liver transplants by over 1,000, and compared to the higher performing centers the decrease was even larger. This study did not, however, tie its estimates to the performance standards in the 2007 rule (which are similar but not identical to SRTR standards), to sanctions under that rule, or to specific center decisions, such as removing candidates from the wait list. Hence, while it certainly contributes to the body of scholarship indicating that since 2007 transplants have been performed in a more concentrated set of programs, it does not appear to provide direct estimates of the quantitative effects of the 2007 rule on overall numbers of liver transplants.

Taking into account all the various uncertainties involved in these studies, we do not believe that we can estimate the effects of the 2007 rule on numbers of transplantations for any organ other than kidneys, and that even for kidneys there is no clear central estimate of likely quantitative effects. The wide variation in published results, and the disclaimers as to the various uncertainties involved, make a precise as well as reliable estimate all but impossible and would render arbitrary any non-zero lower bound estimate of health and longevity impacts. (As noted above, however, even in the absence of health and longevity effects, there may be other benefits, such as reduced travel costs, if the proposed rule reduces concentration of transplants in a smaller number of facilities.) Therefore, we have shown the effects of the proposed change as ''not quantified.'' This is not unusual in Regulatory Impact Analyses that address complex phenomena that cannot be measured directly, or whose effects are intertwined with other changing circumstances. That said, we welcome any additional information that might allow a quantitative estimate in the final rule.

Every transplant quality organ that is used for transplantation rather than discarded has a very high probability of substantially extending the life of the recipient. There is a particularly extensive literature on life expectancy before and after transplant, quality of life, and cost savings for kidney patients. A literature synthesis on ''The Cost-Effectiveness of Renal Transplantation,'' by Elbert S. Huang, Nidhi Thakur, and David O. Meltzer, in Sally Satel, *When Altruism Isn't Enough* (AEI Press, 2008) found essentially universal agreement that kidney transplants were not only substantially life extending, but also cost reducing. The authors performed an extensive literature search and found that from 1968 to 2007 seventeen studies assessed the cost-effectiveness of renal transplantation. The authors concluded that ''Renal transplantation . . . is the most beneficial treatment option for patients with end-stage renal disease and is highly cost-effective compared to no therapy. In comparison to dialysis, renal transplantation has been found to reduce costs by nontrivial amounts while improving health both in terms of the number of years of life and the quality of those years of life'' (page 31). More recent studies have reached similar conclusions, as have other syntheses. For example, the ''Systematic Review: Kidney Transplantation Compared with Dialysis in Clinically Relevant Outcome'' (M. Tonelli, N. Wiebe, G. Knoll, A. Bello, S. Browne, D. Jadhov, S. Klarenbach, and J. Gill, American Journal of Transplantation 2011: 2093–2109) focused on life expectancy and quality of life. This article reviewed 110 studies, and concluded that the vast majority showed major improvement in life quality and reductions in mortality among transplant recipients compared to those remaining on dialysis. The *Annual Data Report* of the United States Renal Data System utilizes national data on ESRD, and reports that deaths per 1,000 patient years are about 180 for dialysis patients and about 32 for transplant recipients (see 2016 report, volume 2, Figure i.13 and Tables H.4 and H.10; accessed at *https://www.usrds.org/adr.aspx*). There are similar data on other organs. For example, in 1998, HHS published a final rule with comment period that established governance procedures for the OPTN (63 FR 16296). In the RIA for that rule, the Department estimated that ''the annual benefits of organ transplantation include about eleven thousand lives vastly improved by kidney transplantation, and another eight thousand lives both vastly improved and prolonged by transplantation of other major organs'' (63 FR 16323).

Even without a robust aggregate estimate of likely increases in organ utilization as a result of this proposed regulatory change, the potential benefits are very substantial. For each new kidney transplantation, there would be an average of 10 additional life years per transplant patient compared to those on dialysis (see Wolfe A. et al., ''Comparisons of Mortality in All Patients on Dialysis, Patients on Dialysis Awaiting Transplantation, and Recipients of a First Cadaveric Transplant,'' NEJM, 1999, 341:1725–30; accessed at *http://www.nejm.org/doi/full/10.1056/NEJM199912023412303#t=article*). Valuing each year of life gained using a ''value of a statistical life year'' (VSLY) of $490,000 in 2014 dollars, the total benefits from each additional transplantation in 2018 would be $4.9 million before discounting and $4.4 million after inflating to 2016 dollars and discounting at either 3 percent over the 10-year period (life-year figure for 2014 from Office of the Assistant Secretary for Planning and Evaluation, HHS, Guidelines for Regulatory Impact Analysis, 2016, page 21, accessed at *https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis*). The HHS methodology produces the same result at either discount rate in order to reach the same predetermined ''real'' value. For an explanation and justification of this VSLY approach, see Cass R. Sunstein, ''Lives, Life-Years, and Willingness to Pay,'' 104 Columbia Law Review [i] (2004).

Those HHS guidelines also explain in some detail the concept of quality adjusted life years. The key point to understand is that these are research-based estimates of the value that people

are willing to pay for life-prolonging and life-improving health care interventions of any kind (see sections 3.2 and 3.3 of the HHS Guidelines for a detailed explanation). The QALY amount used in any estimate of overall benefits is not meant to be a precise estimate, but instead is a rough statistical measure that allows an overall estimate of benefits expressed in dollars.

An alternative and more sophisticated analysis would take into account that the life-extending effect of a kidney transplant is not its first effect, but typically follows a number of years off dialysis, until the organ fails and the patient returns to dialysis or is retransplanted. Such an analysis can be found in a recent study by P.J. Held et al., ''A Cost-Benefit Analysis of Government Compensation of Kidney Donors,'' American Journal of Transplantation, 2016, pages 877–885 (plus 65 pages of supplementary details explaining all assumptions, data sources, and calculations). The largest differences between the base case estimated in that study and the preceding estimates is that this RIA uses the considerably higher value of a statistical year of life under HHS guidelines, and this RIA uses the full value of a statistical life year without a ''quality'' adjustment for the added years of life (we use QALYs only for the improved quality of life during years that would otherwise be on kidney dialysis). Under such an estimation approach, potential life-extending benefits could be somewhat larger. For example, if the proposed reform increased the number of life-extending kidney transplants by only 100 a year, and the benefits of both additional life years and QALY gains were estimated at $5.1 million per patient, its total annual benefits for kidney patients would be approximately $510 million a year (100 × $5.1 million).

There are additional benefits from kidney transplantation. As previously discussed, kidney transplants do reduce medical costs, with ''breakeven'' after about 5 years and net savings of several hundred thousand dollars per patient. Other organ transplants create lesser or no medical savings because the alternative is not dialysis. Clearly, however, these kidney transplant savings are small in relation to the life-extending benefits. We have not estimated medical savings or costs for kidneys or other organs in this RIA because any such estimates would depend on the number of additional transplants that we have not estimated.

We welcome comments on the quantitative and non-quantitative portions of the preceding discussion and seek any empirical evidence that would allow robust estimates of benefits, and in particular robust quantitative estimates of the number of patients deprived of transplantation as a result of the 2007 rule, as currently implemented to reflect the 2016 guidance, for each organ type. We also welcome comments on whether we have accurately and reasonably summarized the research evidence on the effects of the 2007 rules, particularly in the light of the many other factors influencing transplantation trends and performance.

We note that life-extending estimates are averages across patients who vary widely in age, medical condition, and life expectancy, as well as type of organ failure. For example, the sickest patients typically have very low life expectancies without transplant, and hence stand to gain the most years of life from a transplant. Partly offsetting this, these same patients, on average, have slightly lower survival rates post-transplant. Organ and patient survival issues are complex and dealt with by detailed policies and procedures developed and used by the transplant community under the auspices of the OPTN. These policies are reviewed and revised frequently based on actual experience and changing technology—over time the success rate from previously marginal organs, and in older patients, have both increased substantially. For purposes of this analysis, the proper measure is the average gain across all patients who would receive transplants as a result of eliminating the 2007 rule, net of these other factors.

There could be potential offsets to these calculated and uncalculated benefits and cost reductions. However, the particular regulatory requirements we propose to remove are unlikely to drive any further significant increases in graft and patient survival. For renal transplants, the expected 1-year graft and patient survival rates are already at 95 percent or better. Transplant program outcomes will continue to be monitored by the OPTN and programs that are not in compliance with the OPTN outcomes are referred to their Membership and Professional Standards Committee for quality improvement activities. The SRTR also publishes detailed data on transplant program performance that allows patients and their physicians to compare transplant programs and this transparency creates pressures to maintain and improve survival rates in order to attract these patients.

The current regulatory requirements for transplant centers, as discussed in section II.E ''Transplant Centers'' of this proposed rule, have created both positive and adverse incentives for transplant programs, with unanticipated side effects on both utilization of donated organs and the ability of the highest risk patients to obtain transplants. We expect the proposed change to provide substantial net benefits, particularly since other regulatory and informational incentives remain in place.

We welcome comments on this analysis as well as information that would enable a more robust quantitative analysis of the impacts of this change and on any alternative reforms that might provide even higher benefits.

6. Effects on HHAs

As of May 2017 there are 12,624 HHAs that participate in Medicare and Medicaid. In the January 2017 HHA CoP final rule (82 FR 4149) we estimated that compliance with the requirements at § 484.50(a)(3) related to providing oral notice of all rights to each patient would impose a burden of 5 minutes per patient, or 330,246 hours of burden nationwide at a cost of $80,030,370, annually. The cost estimate was based on a $63 per hour estimate for the services of a RN as derived from the BLS Occupational Handbook, 2014–2015 edition, including a 100 percent benefit and overhead package. Adjusted to reflect more updated salary information, as described previously, we estimate that compliance with this provision would impose a $91,786,974 burden, based on a RN earning $69 per hour.

We propose to revise the verbal notification requirements to limit them to those that are required by section 1891 of the Act. Limiting the amount of information that is required to be provided orally will reduce the time per patient that is required to comply with the revised requirement. For purposes of this analysis only, we assume that providing oral notice regarding financial liability only will require 2 minutes per patient, reducing burden by 60 percent. Based on this assumption, this proposed change would reduce the burden of the patient rights notification requirement by 198,148 hours (330,246 hours originally estimated × 0.6) and $55,072,184 ($91,786,974 burden as updated to reflect more recent salary estimates × 0.6).

We also propose two changes that do not have a savings estimate. First, we propose to eliminate the requirement at § 484.80(h)(3) that the HHA conduct a full competency evaluation of deficient home health aides, and replace it with a requirement to retrain the aide regarding the identified deficient skill(s) and require the aide to complete a competency evaluation related to those

skills. As we stated in the January 2017 HHA CoP final rule (82 FR 4575), it is standard practice within the HHA industry to supervise home health aides, and the regulatory requirements for such supervision do not impose any additional burden.

Second, we propose to remove the requirement at § 484.110(e) related to providing a requested copy of the clinical record at the next home visit, while retaining the requirement to provide the record within 4 business days. As stated in the January 2017 HHA CoP final rule (82 FR 4568 and 4575), we believe that providing such information to patients is a usual and customary practice that does not impose a burden upon HHAs. As such, removing the ''next home visit'' timeframe requirement would not result in a savings of burden hours or dollars.

We welcome public comment regarding these burden estimates, and additional regulatory reforms to reduce the burden of the HHA CoPs.

7. Effects on CAHs

We propose to remove the requirement at § 485.627(b)(1) for CAHs to disclose to CMS its owners or those with a controlling interest in the CAH or any subcontractor in which the CAH directly or indirectly ha a 5 percent or more ownership interest in accordance with 42 CFR part 420, subpart C. We discuss the economic impact of this provision in the ICR section, which is estimated at $141,000 total for all CAHs. We discussed the burden reduction for our proposed revision of the ''patient care policies'' requirements imposed on CAHs in the ICR section of this rule, which is estimated at $2.5 million.

8. Effects on CORFs

We discussed the burden reduction for our proposed revision of the ''utilization review plan'' requirements imposed on CORFs in the ICR section of this rule, which is estimated at $309,072.

9. Effects on CMHCs

We discussed the burden reduction for our proposed revision of § 485.914(d)(1) ''update of the comprehensive assessment'' requirements imposed on CMHCs in the ICR section, which is an estimated savings of $152,464.

10. Effects on Portable X-Ray Services

At § 486.104 we propose to revise the portable x-ray CfCs to focus on the qualifications of the technologist performing the diagnostic test. As of May 2017 there were approximately 500 Medicare-participating portable x-ray suppliers employing an estimated 5,000 portable x-ray technologists. Hiring limited x-ray technologists or those with State licensure would allow portable x-ray suppliers to fill vacant positions at a lower hourly cost. Assuming a 10 percent annual turnover rate, all technologists could be hired at the lower salary over a period of 10 years. Limited x-ray technologists can be hired for approximately $30 an hour ($62,400 per year), whereas, according to the BLS, x-ray technologists with advanced certification (ARRT) are hired at a rate of approximately $60 dollars per hour ($124,800 per year). This creates a savings opportunity of $30 per hour, or $62,400 per year, per technologist position. Based on an assumed 10 percent turnover rate, or 500 positions filled in any given year, this change would create a savings of $31,200,000 savings in the first year. We believe that these savings would be increased every year as more positions are filled at the lower salary rate.

We welcome public comment regarding these burden estimates, and additional regulatory reforms to reduce the burden of the portable x-ray CfCs.

11. Effects on RHCs and FQHCs

We discussed the burden reduction for our proposed revision of § 491.9(b)(4) ''review of patient care policies'' requirements imposed on RHCs and FQHCs in the ICR section, which is an estimated savings of $6.8 million. In addition, the burden reduction for our proposed revision of § 491.11(a) ''program evaluation'' requirements imposed on RHCs and FQHCs in the ICR section of this rule, which is an estimated savings of $9.4 million.

12. Effects of Emergency Preparedness Requirements on Providers and Suppliers

This proposed rule revises the emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers, as discussed in detail in section II.M of this proposed rule. The proposed modifications to the emergency preparedness requirements either simplify the requirements, eliminate duplicative requirements, or reduce the frequency in which providers would need to comply with the emergency preparedness requirements. We estimate that the proposed changes to the emergency preparedness requirements would accrue an annual cost savings of $155 million in total. The potential, estimated cost savings for each revised emergency preparedness requirement is outlined in detail below. The methodology used to calculate the economic impact and the costs associated with the proposed changes to the emergency preparedness requirements is the same methodology used to calculate the economic impact in the Emergency Preparedness final rule (81 FR 63860).

At § 482.15(a), (b), (c), and (d) for hospitals and parallel regulatory citations for other facilities, we propose to allow providers to review their program at least every 2 years. We discuss the economic impact for this requirement in the ICR section of this rule, which represents $94,312,719 in savings.

At § 482.15(a)(4) for hospitals, and other parallel citations for the facilities mentioned in section II.J.2 of this proposed rule, we propose to eliminate the requirement that facilities document efforts to contact local, tribal, regional, State, and Federal emergency preparedness officials and that facilities document participation in collaborative and cooperative planning efforts. We discuss the economic impact for this requirement in the ICR section of this rule, which represents $7,179,117 in savings.

At § 482.15(d)(1)(ii) for hospitals, and other parallel citations for other facilities mentioned in section II.J.2 of this proposed rule, we propose to require that facilities provide training biennially, or every 2 years, after facilities conduct initial training on their emergency program. In addition, we propose to require additional training when the emergency plan is significantly updated. We discuss the economic impact for this requirement in the ICR section of this rule, which represents $33,267,864 in savings. Finally, at § 482.15(d)(2), we propose to require that providers of inpatient services mentioned in section II.J.2 of this proposed rule conduct two testing exercises annually, one of which may be an exercise of their choice that must be either a community-based full-scale exercise (if available), an individual facility-based functional exercise, a drill, a tabletop exercise or workshop that includes a group discussion led by a facilitator. We propose to require that providers of outpatient services mentioned in section II.J.2 of this proposed rule conduct one testing exercise annually which must be either a community-based full-scale exercise (if available) or an individual facility-based functional exercise every other year, and in the opposite years, may be either a community-based full-scale exercise (if available), a facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator. We

discuss the majority of this economic impact for this requirement in the ICR section, which represents $9,117,425 in savings. We do not estimate any economic impact for the providers of inpatient services as we are not proposing any changes to the number of testing exercises that must be conducted by these providers; however, we estimate an additional economic impact for this provision for each outpatient provider due to a reduction in the testing requirement from two exercises per year to one exercise per year. We would like to note that for CORFs and Organizations, consistent with the Emergency Preparedness Final Rule (*Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers; Final Rule,* 81 FR 63860), the CoPs for these providers previously required them to have ongoing drills and exercises to test their disaster plans. Therefore, we continue to expect, as we did in the Emergency Preparedness final rule, that the economic impact to comply with this requirement will be minimal, if any. Therefore, the total economic impact of this provision for CORFs and Organizations will be limited to the estimated ICR burden of $55,272 and $305,172, respectively.

We estimate a total impact savings of $10,997,373 for this proposed change. With an estimated ICR savings of $9,117,425, we estimate that the total economic impact of this rule for the affected providers will be $20,114,798. We list a summary of the calculation for the impact savings accrued by removing this requirement for each facility in Table 15, based on facility numbers available as of May 2017.

- *ASCs:* Combined total savings of $1,967,178 for 5,557 ASCs ((4 hours for an administrator at $108 per hour plus 4 hours for a registered nurse at $69 per hour) × 5,557 ASCs × 50 percent).
- *Outpatient Hospice:* Combined total savings of $1,405,920 ((4 hours for an administrator at $105 per hour plus 4 hours for a registered nurse at $69 per hour) × 4,040 outpatient hospices × 50 percent).
- *PACE:* Combined total savings of $16,077 ((1 hour home for a care coordinator at $69 per hour plus 1 hour for a quality improvement nurse at $69) × 233 PACEs × 50 percent).
- *HHAs:* Combined total savings of $2,632,104 ((2 hours for an administrator at $105 per hour plus 3 hours for a director of training at $69 per hour) × 12,624 HHAs × 50 percent).
- *CMHCs:* Combined total savings of $58,926 ((5 hours for an administrator at $105 per hour plus 3 hours for a nurse at $69 per hour) × 161 CMHCs × 50 percent).
- *OPOs:* Combined total savings of $5,046 ((1 hour for a QAPI Director at $105 per hour plus 1 hour for an education coordinator at $69 per hour) × 58 OPOs × 50 percent).
- *RHCs/FQHCs:* Combined total savings of $ 4,187,832 (((4 hours for an administrator at $105 per hour plus 4 hours for a registered nurse at $69 per hour) × 4,160 RHCs × 50 percent) plus (4 hours for an administrator at $105 per hour plus 4 hours for a registered nurse at $69 per hour) × 7,874 FQHCs × 50 percent).
- *ESRDs:* Combined total savings of $724,290 ((1 hour for an administrator at $105 per hour plus 1 hour for a nurse manager at $105 per hour) × 6,898 dialysis facilities × 50 percent).

TABLE 15—COST SAVINGS FOR EMERGENCY PREPAREDNESS TESTING

Provider/supplier	Cost savings per provider/ supplier	Combined total savings
ASCs	$354	$1,967,178 for 5,557 ASCs.
Hospices (outpatient)	348	$1,405,920 for 4,040 outpatient hospice facilities.
PACEs	69	$16,077 for 233 PACEs.
HHAs	209	$2,632,104 for 12,624 HHAs.
CMHCs	366	$58,926 for 161 CMHCs.
OPOs	87	$5,046 for 58 OPOs.
RHCs/FQHCs	348	$4,187,832 for RHCs and FQHCs ($1,447,680 for 4,160 RHCs and $2,740,152 for 7,874 FQHCs).
ESRD Facilities	105	$724,290 for 6,898 dialysis facilities.

13. One-Time Implementation Costs

All of the changes presented above will necessarily have to be read, and understood, and implemented by affected providers. This will create one-time costs even though the underlying change reduces burden. In most cases these costs will be very low, and may be as simple as observing that a particular procedure will need only to be performed once rather than twice a year, and changing the schedule accordingly. In some cases, the facility will need to adjust in response to multiple burden reduction changes. In still other cases, time will have to be spent deciding how to change existing policy. For example, as discussed previously, ASCs and hospital outpatient facilities will need to decide whether and in what circumstances medical histories and physical examinations will be required or encouraged as a matter of policy. Rather than attempt to estimate these situational variables in detail for each facility type, we believe it possible to make reasonable overall estimates of these one-time costs, recognizing that there will be considerable variations among provider types and among individual providers.

In total, there are about 122 thousand affected entities, as shown in the Table 17 that follows. We assume that on average there will be 1 hour of time spent by a lawyer, 2 hours of time by an administrator or health services manager, and 2 hours of time by other staff (we assume registered nurses or equivalent in wage costs) of each affected provider to understand the regulatory change(s) and make the appropriate changes in procedures. We further estimate that for one tenth of these providers, 2 hours of physician time will be needed to consider changes in facility policy. Average hourly costs for these professions, with wage rates doubled to account for fringe benefits and overhead costs, are $134 for lawyers, $105 for managers, $70 for registered nurses, and $198 for physicians. These numbers are from BLS statistics for 2016, at *https://www.bls.gov/oes/2016/may/oes_nat.htm.*

The estimated costs for an average provider would therefore be 1 hour at $134 and in total for the lawyers, 2 hours at $105 or $210 in total for the managers, 2 hours at $69 or $138 in total for the other staff, and two-tenths of 1

hour at $198 or $40 in total for the physicians. These one-time costs add up to $522 per provider on average, and in total to about $64 million.

TABLE 16—ONE-TIME IMPLEMENTATION COSTS

Provider type	Number of affected providers
Religious Nonmedical Health Care Institutions	18
Ambulatory Surgical Centers and hospital outpatient	10,587
Hospices	4,602
Hospitals	5,031
Transplant programs	750
Home Health Agencies	12,624
Critical Access Hospitals	1,343
Comprehensive Outpatient Rehabilitation Facilities	188
Community Mental Health Centers	52
Portable X-Ray Services	500
Rural Health Clinics and Federally Qualified Health Centers	12,034
Emergency Preparedness of Providers and Suppliers	74,246
Total Number of Providers	122,180
Average Cost Per Provider	$522
Total One-Time Cost	$63,777,960

13. Effects on Small Entities, Effects on Small Rural Hospitals, Unfunded Mandates, and Federalism

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that almost all health care providers regulated by CMS are small entities as that term is used in the RFA (including small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year, varying by type of provider and highest for hospitals). Accordingly, almost all of the savings that this proposed rule would create will benefit small entities. We note that individual persons are not small entities for purposes of the RFA, and hence the life-extending transplantation benefits of the proposed rule are not relevant to the RFA.

The RFA requires that a Regulatory Flexibility Analysis (RFA) be prepared if a proposed rule would have a ''significant impact on a substantial number'' of such entities. HHS interprets the statute as mandating this analysis only the impact is adverse, though there are differing interpretations. Regardless, there is no question that this proposed rule would affect a ''substantial number'' of small entities. As shown in Table 17, the total number of affected entities will be about 122,000, including those affected by more than one provision. The rule of thumb used by HHS for determining whether an impact is ''significant'' is an effect of 3 percent or more of annual revenues. These savings do not approach that threshold. Hospitals account for about one-third of all health care spending and even if all these savings accrued to hospitals this threshold would not be approached. Therefore, the Secretary has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. For the reasons previously given, the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately $148 million. This proposed rule contains no mandates that will impose spending costs on State, local, or tribal governments, or on the private sector. Indeed, it substantially reduces existing private sector mandates.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. This proposed rule imposes no such requirements. Importantly, it would remove Federal requirements setting qualification standards for hospice aides. Setting qualifications for health care workers is traditionally a State function, and this change would therefore remove an infringement on State prerogatives.

14. Effects on Costs to Facilities, Providers, Medicare, Other Insurance, and Patients

Most of the individual proposals addressed in the preceding analysis involve reducing burdensome costs on facilities, health care professionals, and patients. Most of those reductions save time and effort currently performed on tasks that we propose to eliminate or reform and those reductions will result ultimately in reduced medical care costs in these facilities, some of which will result in further effects on public and private insurance costs. In this regard, it is important to emphasize that the CoPs and CfCs generally apply to all patients served by a Medicare and/or Medicaid participating provider or supplier, not just Medicare or Medicaid patients, and

to the entire operations of the provider. Revisions to those requirements apply broadly to the entire health care system. We are hopeful that cost reductions ultimately flow to reductions in charges, to reductions in third party payments, and hence to reductions in insurance costs and to those who pay those costs.

In total, we estimate that the approximately 40 specific provisions summarized in Tables 1 and 2 that are not related to reductions in pre-operative physical examinations and tests in outpatient surgery, or to transplantation, will save facilities and other providers, insurers, and patients about $669 million annually. The initial savings will accrue primarily to providers. How much of these savings will flow to insurers and patients depends primarily on the payment and reimbursement mechanisms in place for each affected entity for those particular costs. According to the National Health Expenditure Accounts, approximate payer shares in 2016 were 11 percent for consumer out of pocket, 35 percent for private health insurance, 21 percent for Medicare, 18 percent for Medicaid, and 15 percent for other public and private payers such as the Department of Veteran Affairs and the Department of Defense. We would expect savings to approximate these shares. Ultimately, all costs are paid by workers and taxpayers who pay for all health care directly or indirectly, quite apart from immediate cost subsidies or cost sharing.

Two provisions directly reduce Medicare and other insurance costs. Eliminating unnecessary patient history and physical examinations and medical tests for procedures (such as cataract surgery) performed in ASCs and in hospital outpatient surgery will disproportionately reduce Medicare costs, since use of these services rises with age. Additional transplantation of kidneys will reduce Medicare's ESRD costs, partially offset by increased transplantation costs. Because of the difficulty in finding evidence of the volume of such savings, we cannot estimate the likely effects on Medicare spending.

Most of the facility and provider savings will accrue to Medicare and other insurers over time as payment rate increases are slightly reduced, and the remainder will accrue to other payers and to patients.

The following table shows our estimates of savings by major burden reduction category and by type of payer.

TABLE 17—SAVINGS BY MAJOR PAYER CATEGORIES

[$ Millions]

Savings to:	Ambulatory surgery	Transplant programs	All other cost reductions	Total
Medicare	123	not estimated	141	264
Medicaid	57	not estimated	120	177
Private Insurance	110	not estimated	234	344
Other Payers	47	not estimated	100	147
Patients	117	not estimated	74	191
Total	454	not estimated	669	1,123

Note: Calculations based largely on payer percentages in ''National Health Care Spending in 2016,'' Health Affairs, January 2018, pages 150–160. Patient share for ambulatory surgery savings reflects travel time, not medical costs.

15. Benefits to Patients

We discussed life-extending and life-saving benefits at length in the analysis of increases in transplantation. These result from removal of disincentives to transplant patients, or to use organs, where this could reduce success rates by a few percent and possibly trigger closure of transplant centers or programs under current rules. As previously explained, we do not have robust estimates. There are additional and substantial patient benefits likely to result from the cost-reducing reforms that we propose. Time not wasted by medical care providers or facilities on unnecessary tasks is time that can be used to focus on better care. While such effects could be measured in principal, there is little existing data on magnitudes of such effects. We do, however, welcome public comments on these or any other aspects of costs and benefits of the proposed rule.

D. Alternatives Considered

From within the entire body of CoPs and CfCs, we selected what we believe to be the most viable candidates for reform as identified by stakeholders, by recent research, or by experts as unusually burdensome. This subset of the universe of standards is the focus of this proposed rule. For all of the proposed provisions, we considered not making these changes. Ultimately, we saw no good reasons not to propose these burden reducing changes.

We welcome comments on whether we properly selected the best candidates for change, and welcome suggestions for additional reform candidates from the entire body of CoPs and other regulatory provisions that fall directly on providers.

E. Uncertainty

Our estimates of the effects of this regulation are subject to significant uncertainty. While the Department is confident that these reforms will provide flexibilities to facilities that will yield major cost savings, there are uncertainties about the magnitude of these effects. Despite these uncertainties, we are confident that the rule will yield substantial overall cost reductions and other benefits. In this analysis we have provided estimates to suggest the potential savings these reforms could achieve under certain assumptions. We appreciate that those assumptions are simplified, and that actual results could be substantially higher or lower. Although there is uncertainty concerning the magnitude of all of our estimates, we do not have the data to provide specific estimates for each reform proposed, as to the range of possibilities, or to estimate all categories of possible benefits, including health effects.

F. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in Table 18, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this proposed rule.

While most provisions of the proposed rule have clearly predictable effects we do not in most cases have detailed empirical information on the precise magnitude of efforts involved (for example, time spent in meeting paperwork or other administrative tasks

that apply to a particular provider type). Other provisions (notably those related to organ transplantation and removal of strict H & P requirements before ambulatory surgery) have even more uncertain effect sizes. Therefore, we have estimated an upper and lower level for benefit and cost reduction estimates that is 25 percent higher or lower than our primary estimate for all quantified reforms other than those related to ambulatory surgery, and in that area our lower bound is zero cost reductions and our upper bound is a 50% reduction in H&P and associated laboratory testing costs.

TABLE 18—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED BENEFITS AND SAVINGS

[$ Millions]

Category	Primary estimate	Lower bound	Upper bound	Units		
				Year dollars	Discount rate (%)	Period covered
Life-Extending Benefits (monetized)	Not Quantified					
Medical Cost Reduction Benefits (monetized)	Not Quantified					
Other Cost Reductions (monetized)	−$1,240 −$1,250	−$580 −$590	−$1,890 −$1,900	2016 2016	7 3	2018 onward. 2018 onward.
Costs	None					
Transfers	None					

G. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This proposed rule will, if finalized as proposed, be considered an E.O. 13771 deregulatory action. We estimate that this rule generates $1,051 million in annualized cost savings, discounted at 7 percent relative to year 2018, over a perpetual time horizon. This estimate is based on cost reductions starting at $1,123 million, and growing by $31 million annually due to salary savings from X-ray technician turnover, partially offset by one-time first-year implementation costs of $64 million, all in 2016 dollars. Details on the estimated cost savings from this rule can be found in the preceding analysis. We note that public comments and additional information may enable us to estimate considerably larger savings from reforming H & P requirements for ambulatory surgery or to narrow the uncertainty within the range of the preliminary estimates.

H. Conclusion

This proposed rule would substantially reduce existing regulatory requirements imposed on health care providers through the CoPs and related regulatory provisions that Medicare and Medicaid providers must meet. For some provisions, health benefits to patients will be substantial and direct. Other provisions will free up time and efforts of health care providers to focus on improving health care quality and service delivery. Although this proposed rule does not require an Initial Regulatory Flexibility Analysis, this regulatory impact analysis, together with the remainder of this preamble, meets the requirements for such an analysis. Furthermore, the analysis in this section of the preamble, together with the remainder of this preamble, provides a complete Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 403

Grant programs—health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 441

Aged, Family planning, Grant programs-health, Infants and children, Medicaid, Penalties, reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant program—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing home, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 486

Grant programs—health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 488

Administrative practice and procedures, Health facilities, Health professions, Medicare, reporting and recordkeeping requirements.

42 CFR Part 491

Grant programs—health, Health facilities, Medicaid, Medicare,

Reporting and recordkeeping requirements, Rural and Urban areas.

42 CFR Part 494

Health facilities, Diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 continues to read as follows:

Authority: 42 U.S.C. 1395b-3 and Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 403.736 is amended by—
■ a. Removing the introductory text;
■ b. Revising paragraph (a);
■ c. Removing paragraph (b); and
■ d. Redesignating paragraphs (c) and (d) as paragraphs (b) and (c).

The revision reads as follows:

§ 403.736 Condition of participation: Discharge planning.

(a) *Discharge planning and instructions.* The RNHCI must have in effect a discharge planning process that applies to all patients. The process must assure that appropriate post-institution services are obtained for each patient, as necessary. The RNHCI must assess the need for a discharge plan for any patient likely to suffer adverse consequences if there is no planning.

(1) Discharge instructions must be provided at the time of discharge to the patient or the patient's caregiver as necessary.

(2) If the patient assessment indicates a need for a discharge plan, the discharge plan must include instructions on post-RNHCI care to be used by the patient or the caregiver in the patient's home, as identified in the discharge plan.

(3) If the RNHCI's patient assessment does not indicate a need for a discharge plan, the beneficiary or his or her legal representative may request a discharge plan. In this case, the RNHCI must develop a discharge plan for the beneficiary.

* * * * *

■ 3. Section 403.748 is amended by—
■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii); and
■ b. Adding paragraph (d)(1)(v).

The revisions and addition read as follows:

§ 403.748 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The RNHCI must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The RNHCI must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The RNHCI must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The RNHCI must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the RNHCI must conduct training on the updated policies and procedures.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

■ 4. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320–8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273)).

§ 416.41 [Amended]

■ 5. Section 416.41 is amended by removing paragraph (b)(3).

■ 6. Section 416.47 is amended by revising paragraph (b)(2) to read as follows:

§ 416.47 Condition for coverage—Medical records.

* * * * *

(b) * * *

(2) Significant medical history and results of physical examination (as applicable).

* * * * *

■ 7. Section 416.52 is amended by revising the section heading and paragraph (a) to read as follows:

§ 416.52 Condition for coverage—Patient admission, assessment and discharge.

* * * * *

(a) *Standard: Patient assessment and admission.* (1) The ASC must develop and maintain a policy that identifies those patients who require a medical history and physical examination prior to surgery. The policy must—

(i) Include the timeframe for medical history and physical examination to be completed prior to surgery.

(ii) Address, but is not limited to, the following factors: Patient age, diagnosis, the type and number of procedures scheduled to be performed on the same surgery date, known comorbidities, and the planned anesthesia level.

(iii) Follow nationally recognized standards of practice and guidelines, and applicable State and local health and safety laws.

(2) Upon admission, each patient must have a pre-surgical assessment completed by a physician who will be performing the surgery or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(3) The pre-surgical assessment must include documentation of any allergies to drugs and biologicals.

(4) The patient's medical history and physical examination (if any) must be placed in the patient's medical record prior to the surgical procedure.

* * * * *

■ 8. Section 416.54 is amended by—
■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);
■ b. Adding paragraph (d)(1)(v); and
■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 416.54 Condition for coverage—Emergency preparedness.

* * * * *

(a) *Emergency plan.* The ASC must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The ASC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The ASC must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The ASC must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the ASC must conduct training on the updated policies and procedures.

(2) *Testing.* The ASC must conduct exercises to test the emergency plan at least annually. The ASC must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, individual, a facility-based functional exercise every 2 years. If the ASC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ASC is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based, or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the ASC's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the ASC's emergency plan, as needed.

* * * * *

PART 418—HOSPICE CARE

■ 9. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 10. Section 418.76 is amended by revising paragraph (a)(1)(iv) to read as follows:

§ 418.76 Condition of participation: Hospice aide and homemaker services.

* * * * *

(a) * * *

(1) * * *

(iv) A State licensure program.

* * * * *

■ 11. Section 418.106 is amended by—

■ a. Removing paragraph (a)(1);

■ b. Redesignating paragraph (a)(2) as paragraph (a)(1);

■ c. Adding a new reserved paragraph (a)(2); and

■ d. Revising paragraph (e)(2)(i).

The revision reads as follows:

§ 418.106 Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment.

* * * * *

(a) * * *

(2) [Reserved]

* * * * *

(e) * * *

(2) * * *

(i) Safe use and disposal of controlled drugs in the patient's home. The hospice must have written policies and procedures for the management, use, storage, and disposal of controlled drugs in the patient's home. At the time when controlled drugs are first ordered the hospice must:

(A) Provide information regarding the use, storage, and disposal of controlled drugs to the patient or patient representative and family in a format that is available on a continual basis;

(B) Discuss the information regarding the safe use, storage and disposal of controlled drugs with the patient or representative, and the family, in a language and manner that they understand to ensure that these parties are effectively educated; and

(C) Document in the patient's clinical record that the information was provided and discussed.

* * * * *

■ 12. Section 418.112 is amended by adding paragraph (c)(10) and removing paragraph (f) to read as follows:

§ 418.112 Condition of participation: Hospices that provide hospice care to residents of a SNF/NF or ICF/IID.

* * * * *

(c) * * *

(10) A delineation of responsibilities for assuring orientation of SNF/NF or ICF/IID staff furnishing care to hospice patients, to include information regarding the hospice philosophy; hospice policies and procedures regarding methods of comfort, pain control, and symptom management; principles about death, dying, and individual responses to death; patient rights; appropriate forms; and record keeping requirements.

* * * * *

■ 13. Section 418.113 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(iii);

■ b. Adding paragraph (d)(1)(vi);

■ c. Revising paragraph (d)(2); and

■ d. Adding paragraph (d)(3).

The revisions and addition to read as follows:

§ 418.113 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The hospice must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal,

regional, State, or Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The hospice must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The hospice must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The hospice must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(iii) Provide emergency preparedness training at least every 2 years.

* * * * *

(vi) If the emergency preparedness policies and procedures are significantly updated, the hospice must conduct training on the updated policies and procedures.

(2) *Testing for hospices that provide care in the patient's home.* The hospice must conduct exercises to test the emergency plan at least annually. The hospice must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years. If the hospice experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(3) *Testing for hospices that provide inpatient care directly.* The hospice must conduct exercises to test the emergency plan twice per year. The hospice must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise annually. If the hospice experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospice is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least annually that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the hospice's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the hospice's emergency plan, as needed.

* * * * *

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

■ 14. The authority citation for part 441 continues to read as follows:

Authority: Secs. 1102, 1902, and 1928 of the Social Security Act (42 U.S.C. 1302).

■ 15. Section 441.184 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);

■ b. Adding paragraph (d)(1)(v); and

■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 441.184 Emergency preparedness.

* * * * *

(a) *Emergency plan.* The PRTF must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The PRTF must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The PRTF must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The PRTF must develop and maintain an emergency preparedness training program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) After initial training, provide emergency preparedness training every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the PRTF must conduct training on the updated policies and procedures.

(2) *Testing.* The PRTF must conduct exercises to test the emergency plan

twice per year. The PRTF must do the following:

(i) Participate in a full-scale exercise annually that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise annually. If the PRTF experiences an actual natural or man-made emergency that requires activation of the emergency plan, the PRTF is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least annually that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, a facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the PRTF's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the PRTF's emergency plan, as needed.

* * * * *

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 16. The authority citation for part 460 continues to read as follows:

Authority: Secs: 1102, 1871, 1894(f), and 1934(f) of the Social Security Act (42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f)).

■ 17. Section 460.84 is amended by—
■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);
■ b. Adding paragraph (d)(1)(v); and
■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 460.84 Emergency preparedness.

* * * * *

(a) *Emergency plan.* The PACE organization must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The PACE organization must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must address management of medical and nonmedical emergencies, including, but not limited to: Fire; equipment, power, or water failure; care-related emergencies; and natural disasters likely to threaten the health or safety of the participants, staff, or the public. Policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The PACE organization must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The PACE organization must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at lease every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the PACE must conduct training on the updated policies and procedures.

(2) *Testing.* The PACE organization must conduct exercises to test the emergency plan at least annually. The PACE organization must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years. If the PACE experiences an actual natural or man-made emergency that requires activation of the emergency plan, the PACE is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least every 2 years opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the PACE's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the PACE's emergency plan, as needed.

* * * * *

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 18. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

■ 19. Section 482.15 is amended—
■ a. By revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);
■ b. By adding paragraph (d)(1)(v);
■ c. By revising paragraph (d)(2);
■ d. In paragraph (g) introductory text, by removing the phrase ''transplant centers'' and adding into its place the phrase ''transplant programs''; and
■ e. In paragraphs (g)(1) and (2), by removing the phrase ''transplant center'' and adding into its place the phrase ''transplant program''.

The revisions and addition read as follows:

§ 482.15 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The hospital must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to

maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The hospital must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The hospital must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The hospital must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the hospital must conduct training on the updated policies and procedures.

(2) *Testing.* The hospital must conduct exercises to test the emergency plan at least twice per year. The hospital must do all of the following:

(i) Participate in an annual full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise annually. If the hospital experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from engaging in its next required full-scale community-based exercise or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least annually that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the hospital's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan, as needed.

* * * * *

■ 20. Section 482.21 is amended by adding paragraph (f) to read as follows:

§ 482.21 Condition of participation: Quality assessment and performance improvement program.

* * * * *

(f) *Standard: Unified and integrated QAPI program for multi-hospital systems.* If a hospital is part of a hospital system consisting of multiple separately certified hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have a unified and integrated QAPI program for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital subject to the system governing body must demonstrate that:

(1) The unified and integrated QAPI program is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and

(2) The unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.

■ 21. Section 482.22 is amended by—

■ a. Revising paragraphs (c)(5)(i) and (ii);

■ b. Adding paragraphs (c)(5)(iii), (iv), and (v); and

■ c. Removing paragraph (d).

The revisions and additions read as follows:

§ 482.22 Condition of participation: Medical staff.

* * * * *

(c) * * *

(5) * * *

(i) A medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, and except as provided under paragraph (c)(5)(iii) of this section. The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(ii) An updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration, and except as provided under paragraph (c)(5)(iii) of this section. The updated examination of the patient, including any changes in the patient's condition, must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(iii) An assessment of the patient (in lieu of the requirements of paragraphs (c)(5)(i) and (ii) of this section) be completed and documented after registration, but prior to surgery or a procedure requiring anesthesia services, when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at paragraph (c)(5)(v) of this section, specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services. The assessment must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(iv) The medical staff develop and maintain a policy that identifies those patients for whom the assessment requirements of paragraph (c)(5)(iii) of this section would apply. The provisions of paragraphs (c)(5)(iii), (iv), and (v) of this section do not apply to a medical staff that chooses to maintain a policy that adheres to the requirements of paragraphs of (c)(5)(i) and (ii) of this section for all patients.

(v) The medical staff, if it chooses to develop and maintain a policy for the identification of specific patients to whom the assessment requirements in paragraph (c)(5)(iii) of this section would apply, must demonstrate evidence that the policy applies only to those patients receiving specific outpatient surgical or procedural services as well as evidence that the policy is based on:

(A) Patient age, diagnoses, the type and number of surgeries and procedures scheduled to be performed, comorbidities, and the level of anesthesia required for the surgery or procedure.

(B) Nationally recognized guidelines and standards of practice for assessment of specific types of patients prior to specific outpatient surgeries and procedures.

(C) Applicable state and local health and safety laws.

* * * * *

■ 22. Section 482.24 is amended by revising paragraphs (c)(4)(i)(A) and (B) and adding paragraph (c)(4)(i)(C) to read as follows:

§ 482.24 Condition of participation: Medical record services.

* * * * *

(c) * * *

(4) * * *

(i) * * *

(A) A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, and except as provided under paragraph (c)(4)(i)(C) of this section. The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

(B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration, and except as provided under paragraph (c)(4)(i)(C) of this section. Documentation of the updated examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

(C) An assessment of the patient (in lieu of the requirements of paragraphs (c)(4)(i)(A) and (B) of this section) completed and documented after registration, but prior to surgery or a procedure requiring anesthesia services, when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at § 482.22(c)(5)(v), specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services.

* * * * *

■ 23. Section 482.42 is amended by adding paragraph (c) to read as follows:

§ 482.42 Condition of participation: Infection control.

* * * * *

(c) *Standard: Unified and integrated infection control program for multi-hospital systems.* If a hospital is part of a hospital system consisting of multiple separately certified hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have a unified and integrated infection control program for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital subject to the system governing body must demonstrate that:

(1) The unified and integrated infection control program is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital;

(2) The unified and integrated infection control program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration;

(3) The unified and integrated infection control program has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed; and

(4) A qualified individual (or individuals) with expertise in infection prevention and control has been designated at the hospital as responsible for communicating with the unified infection control program, for implementing and maintaining the policies and procedures governing infection control as directed by the unified infection control program, and for providing infection prevention education and training to hospital staff.

■ 24. Section 482.51 is amended by revising paragraphs (b)(1)(i) and (ii) and adding paragraph (b)(1)(iii) to read as follows:

§ 482.51 Condition of participation: Surgical services.

* * * * *

(b) * * *

(1) * * *

(i) A medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration, and except as provided under paragraph (b)(1)(iii) of this section.

(ii) An updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration, and except as provided under paragraph (b)(1)(iii) of this section.

(iii) An assessment of the patient must be completed and documented after registration (in lieu of the requirements of paragraphs (b)(1)(i) and (ii) of this section) when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at § 482.22(c)(5)(v), specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services.

* * * * *

■ 25. Section 482.58 is amended by—

■ a. Revising paragraph (b)(1);

■ b. Removing paragraph (b)(4);

■ c. Redesignating paragraphs (b)(5) through (8) as paragraphs (b)(4) through (7); and

■ d. Revising newly redesignated paragraphs (b)(4) and (7).

The revisions read as follows:

§ 482.58 Special requirements for hospital providers of long-term care services ("swing-beds").

* * * * *

(b) * * *

(1) Resident rights (§ 483.10(b)(7), (c)(1), (c)(2)(iii), (c)(6), (d), (e)(2) and (4), (f)(4)(ii) and (iii), (h), (g)(8) and (17), and (g)(18) introductory text of this chapter).

* * * * *

(4) Social services (§ 483.40(d) of this chapter).

* * * * *

(7) Dental services (§ 483.55(a)(2), (3), (4), and (5) and (b) of this chapter).

■ 26. Section 482.61 is amended by revising paragraph (d) to read as follows:

§ 482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.

* * * * *

(d) *Standard: Recording progress.* Progress notes must be recorded by the physician(s), psychologists, or other licensed independent practitioner(s) responsible for the care of the patient as specified in § 482.12(c), nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

* * * * *

§ 482.68 [Amended]

■ 27. Section 482.68 is amended—

■ a. In the section heading by removing the phrase ''transplant centers'' and adding in its place the phrase ''transplant programs''; and

■ b. In the introductory text and in paragraph (b) by removing the phrase ''transplant center'' and adding in its place the phrase ''transplant program''.

■ 28. Section 482.70 is amended—

■ a. In the definition of ''Adverse event'' by removing the phrase ''transplant centers'' and adding in its place the phrase ''transplant programs'';

■ b. By removing the definitions of ''Heart-Lung transplant center'' and ''Intestine transplant center'';

■ c. By adding the definitions of ''Heart-Lung transplant program'' and ''Intestine transplant program'' in alphabetical order;

■ d. By removing the definitions of ''Pancreas transplant center'' and ''Transplant center'';

■ e. By adding the definition of ''Pancreas transplant program'' in alphabetical order; and

■ f. By revising the definition of ''Transplant program''.

The additions and revision read as follows:

§ 482.70 Definitions.

* * * * *

Heart-Lung transplant program means a transplant program that is located in a hospital with an existing Medicare-approved heart transplant program and an existing Medicare-approved lung program that performs combined heart-lung transplants.

Intestine transplant program means a Medicare-approved liver transplant program that performs intestine transplants, combined liver-intestine transplants, or multivisceral transplants.

* * * * *

Pancreas transplant program means a Medicare-approved kidney transplant program that performs pancreas transplants alone or subsequent to a kidney transplant as well as kidney-pancreas transplants.

* * * * *

Transplant program means an organ-specific transplant program within a transplant hospital (as defined in this section).

§§ 482.72, 482.74, 482.78, and 482.80 [Amended]

■ 29. In the following table, for each section and paragraph indicated in the first two columns, remove the phrase indicated in the third column each time it appears and add the reference indicated in the fourth column:

Section	Paragraphs	Remove	Add
§ 482.72		transplant center	transplant program.
§ 482.74	(a) introductory text	transplant center	transplant program.
§ 482.74	(a) introductory text	center's	hospital's.
§ 482.74	(a)(1)	transplant center	transplant program.
§ 482.74	(a)(1)	center's	program's.
§ 482.74	(a)(2)	transplant center	transplant program.
§ 482.74	(a)(3)	transplant center	transplant program.
§ 482.74	(b) introductory text	transplant center	transplant program.
§ 482.78	Section heading	transplant centers	transplant programs.
§ 482.78	Introductory text	transplant center	transplant program.
§ 482.78	(a)	transplant center	transplant program.
§ 482.78	(b)	transplant center	transplant program.
§ 482.80	Section heading	transplant centers	transplant programs.
§ 482.80	Introductory text	transplant centers	transplant programs.
§ 482.80	(a)	transplant center	transplant program.
§ 482.80	(a)	beneficiary	recipient.
§ 482.80	(b)	transplant center	transplant program.
§ 482.80	(c) introductory text	center	program.
§ 482.80	(c)(1)	transplant center's	transplant program's.
§ 482.80	(c)(1)	center-specific report	program-specific report.
§ 482.80	(c)(1)	Beneficiaries	Recipients.
§ 482.80	(c)(2)	center's	program's.
§ 482.80	(d)(1)	transplant center	transplant program.
§ 482.80	(d)(2)	transplant center	transplant program.
§ 482.80	(d)(3)	transplant center	transplant program.
§ 482.80	(d)(4)	transplant center	transplant program.
§ 482.80	(d)(5)	transplant center	transplant program.

§ 482.82 [Removed]

■ 30. Section 482.82 is removed.

§§ 482.90, 482.92, 482.94, 482.96, 482.98, 482.100, and 482.102 [Amended]

■ 31. In the following table, for each section and paragraph indicated in the first two columns, remove the phrase indicated in the third column each time it appears and add the reference indicated in the fourth column:

Section	Paragraphs	Remove	Add
§ 482.90	Introductory text	transplant center	transplant program.
§ 482.90	Introductory text	center	program.
§ 482.90	(a)(2)	transplant center	transplant program.
§ 482.90	(a)(4)	transplant center	transplant program.
§ 482.90	(b) introductory text	Transplant centers	Transplant programs.
§ 482.92	Introductory text	donor-beneficiary	donor-recipient.
§ 482.92	Introductory text	beneficiary	recipient.
§ 482.92	Introductory text	Transplant centers	Transplant programs.
§ 482.92	Introductory text	transplant center	transplant program.
§ 482.92	(a)	transplant center	transplant program.
§ 482.92	(a)	beneficiary	recipient.
§ 482.92	(b)	beneficiary	recipient.
§ 482.92	(b)	beneficiary's	recipient's.
§ 482.94	Introductory text	Transplant centers	Transplant programs.
§ 482.94	Introductory text	transplant center	transplant programs.
§ 482.94	Introductory text	the center also	the program also.
§ 482.94	(a) introductory text	transplant center's	transplant program's.
§ 482.94	(a)(2)	center	program.
§ 482.94	(b) introductory text	Transplant centers	Transplant programs.
§ 482.94	(b)(2)	center's	program's.
§ 482.94	(b)(3)	center's	program's.
§ 482.94	(c) introductory text	Transplant centers	Transplant programs.
§ 482.94	(c) introductory text	center's waiting list	program's waiting list.
§ 482.94	(c)(2)	transplant center	transplant program.
§ 482.94	(c)(3) introductory text	transplant centers	transplant programs.
§ 482.94	(d) introductory text	transplant center	transplant program.
§ 482.94	(d)(2)	transplant center	transplant program.
§ 482.94	(e)	Transplant centers	Transplant programs.
§ 482.96	Introductory text	Transplant centers	Transplant programs.
§ 482.96	(a)	transplant center's	transplant program's.
§ 482.96	(a)	beneficiary	recipient.
§ 482.96	(a)	transplant center	transplant program.
§ 482.96	(b) introductory text	transplant center	transplant program.
§ 482.96	(b)(2)	transplant center	transplant program.
§ 482.96	(b)(2)	transplant center's	transplant program's.
§ 482.98	Introductory text	transplant center	transplant program.
§ 482.98	Introductory text	the center	the program.
§ 482.98	(a) (a) heading and introductory text	transplant center	transplant program.
§ 482.98	(a)(1)	transplant center	transplant program.
§ 482.98	(b) introductory text	transplant center	transplant program.
§ 482.98	(c) introductory text	transplant center	transplant program.
§ 482.98	(c)(2)	transplant center	transplant program.
§ 482.98	(d) introductory text	transplant center	transplant program.
§ 482.98	(d) heading	living donor advocate team	independent living donor advocate team.
§ 482.98	(d)(1)	living donor advocate	independent living donor advocate.
§ 482.98	(d)(2) introductory text	living donor advocate team	independent living donor advocate team.
§ 482.98	(d)(3) introductory text	living donor advocate team	independent living donor advocate team.
§ 482.98	(e)	transplant center	transplant program.
§ 482.98	(f)	transplant center	transplant program.
§ 482.100		transplant center	transplant program.
§ 482.102	Introductory text	transplant center	transplant program.
§ 482.102	(a) introductory text	Transplant centers	Transplant programs.
§ 482.102	(a)(8)	transplant center	transplant program.
§ 482.102	(a)(8)	beneficiary's	recipient's.
§ 482.102	(b) introductory text	Transplant centers	Transplant programs.
§ 482.102	(b)(1)	transplant center	transplant program.
§ 482.102	(b)(4)	beneficiary	recipient.
§ 482.102	(b)(6)	transplant center-specific	transplant program-specific.
§ 482.102	(b)(6)	beneficiaries	receipients.
§ 482.102	(b)(6)	center-specific outcomes	transplant-specific outcomes.
§ 482.102	(b)(9)	transplant center	transplant program.
§ 482.102	(b)(9)	beneficiary's	recipient's.
§ 482.102	(c) introductory text	Transplant centers	Transplant programs.
§ 482.102	(c) introductory text	center's	program's.
§ 482.102	(c) introductory text	center	program.
§ 482.102	(c)(1) introductory text	transplant center	transplant program.

Section	Paragraphs	Remove	Add
§ 482.102	(c)(1) introductory text	center's waiting list	program's waiting list.
§ 482.102	(c)(2)(i)	center's waiting list	program's waiting list.
§ 482.102	(c)(2)(i)	transplant center	transplant program.
§ 482.102	(c)(2)(ii)	beneficiaries	recipients.
§ 482.102	(c)(2)(ii)	center's waiting list	program's waiting list.
§ 482.102	(c)(2)(ii)	the center	the program.
§ 482.102	(c)(2)(ii)	center's termination of approval	program's termination of approval.
§ 482.102	(c)(3)	transplant center's	transplant program's.
§ 482.102	(c)(3)	the center	the program.
§ 482.102	(c)(3)	center's waiting list	program's waiting list.
§ 482.102	(c)(3)	transplant center	transplant program.

■ 32. Section 482.102 is further amended by revising paragraph (a)(5) to read as follows:

§ 482.102 Condition of participation: Patient and living donor rights.

* * * * *

(a) * * *

(5) National and transplant program-specific outcomes, from the most recent SRTR program-specific report, including (but not limited to) the transplant program's observed and expected 1-year patient and graft survival, and national 1-year patient and graft survival;

* * * * *

§ 482.104 [Amended]

■ 33. For § 482.104, in the following table, for the heading and each paragraph indicated in the first column, remove the phrase indicated in the second column each time it appears and add the reference indicated in the third column:

Paragraphs	Remove	Add
Section heading	transplant centers	transplant programs.
(a)	transplant centers	transplant programs.
(a)	transplant center	transplant program.
(b)	transplant centers	transplant programs.
(c)	transplant centers	transplant programs.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 34. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102, 1128I, 1819, 1871 and 1919 of the Social Security Act (42 U.S.C. 1302, 1320a–7, 1395i, 1395hh and 1396r).

■ 35. Section 483.73 is amended by—
■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);
■ b. Adding paragraph (d)(1)(v); and
■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 483.73 Emergency preparedness.

* * * * *

(a) *Emergency plan.* The LTC facility must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, or Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The LTC facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The LTC facility must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The LTC facility must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the LTC facility must conduct training on the updated policies and procedures.

(2) *Testing.* The LTC facility must conduct exercises to test the emergency plan at least twice per year, including unannounced staff drills using the emergency procedures. The LTC facility must do the following:

(i) Participate in an annual full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise annually. If the LTC facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the LTC facility is exempt from engaging its next required a full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least annually that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by

a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the LTC facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the LTC facility's emergency plan, as needed.

* * * * *

■ 36. Section 483.475 is amended by—
■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);
■ b. Adding paragraph (d)(1)(v); and
■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 483.475 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The ICF/IID must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The ICF/IID must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The ICF/IID must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include the following:

* * * * *

(d) *Training and testing.* The ICF/IID must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years. The ICF/IID must meet the requirements for evacuation drills and training at § 483.470(i).

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the ICF/IID must conduct training on the updated policies and procedures.

(2) *Testing.* The ICF/IID must conduct exercises to test the emergency plan at least twice per year. The ICF/IID must do the following:

(i) Participate in an annual full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise annually. If the ICF/IID experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ICF/IID is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least annually that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the ICF/IID's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the ICF/IID's emergency plan, as needed.

* * * * *

PART 484—HOME HEALTH SERVICES

■ 37. The authority citation for part 484 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

■ 38. Section 484.50 is amended by removing and reserving paragraph (a)(3) and revising paragraph (c)(7) introductory text to read as follows:

§ 484.50 Condition of participation: Patient rights.

* * * * *

(c) * * *

(7) Be advised, orally and in writing, of—

* * * * *

■ 39. Section 484.80 is amended by revising paragraph (h)(3) to read as follows:

§ 484.80 Condition of participation: Home health aide services.

* * * * *

(h) * * *

(3) If a deficiency in aide services is verified by the registered nurse or other appropriate skilled professional during an on-site visit, then the agency must conduct, and the home health aide must complete, retraining and a competency evaluation related to the deficient skill(s).

* * * * *

■ 40. Section 484.102 is amended by—
■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, and (d) introductory text and the first paragraph (d)(1)(ii);
■ b. Redesignating the second paragraph (d)(1)(ii) as paragraph (d)(1)(iv);
■ c. Adding paragraph (d)(1)(v); and
■ d. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 484.102 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The HHA must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The HHA must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The HHA must develop and maintain an

emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The HHA must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the HHA must conduct training on the updated policies and procedures.

(2) *Testing.* The HHA must conduct exercises to test the emergency plan at least annually. The HHA must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years. If the HHA experiences an actual natural or man-made emergency that requires activation of the emergency plan, the HHA is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the HHA's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the HHA's emergency plan, as needed.

* * * * *

■ 41. Section 484.110 is amended by revising paragraph (e) to read as follows:

§ 484.110 Condition of participation: Clinical records.

* * * * *

(e) *Standard: Retrieval of clinical records.* A patient's clinical record (whether hardcopy or electronic form) must be made available to a patient, free of charge, upon request within 4 business days.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 42. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

■ 43. Section 485.66 is amended by revising the introductory text to read as follows:

§ 485.66 Condition of participation: Utilization review plan.

The facility must have in effect a written utilization review plan that is implemented annually, to assess the necessity of services and promotes the most efficient use of services provided by the facility.

* * * * *

■ 44. Section 485.68 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);

■ b. Adding paragraph (d)(1)(v); and

■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 485.68 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The CORF must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

* * * * *

(b) *Policies and procedures.* The CORF must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The CORF must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The CORF must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the CORF must conduct training on the updated policies and procedures.

(2) *Testing.* The CORF must conduct exercises to test the emergency plan at least annually. The CORF must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years. If the CORF experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CORF is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the CORF's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CORF's emergency plan, as needed.

* * * * *

■ 45. Section 485.625 is amended by—
■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);
■ b. Adding paragraph (d)(1)(v); and
■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 485.625 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The CAH must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The CAH must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The CAH must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The CAH must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the CAH must conduct training on the updated policies and procedures.

(2) *Testing.* The CAH must conduct exercises to test the emergency plan at least twice per year. The CAH must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise once per year. If the CAH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CAH is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least annually, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the CAH's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CAH's emergency plan, as needed.

* * * * *

§ 485.627 [Amended]

■ 46. Section 485.627 is amended by removing and reserving paragraph (b)(1).

■ 47. Section 485.635 is amended by revising paragraph (a)(4) to read as follows:

§ 485.635 Condition of participation: Provision of services.

(a) * * *

(4) These policies are reviewed at least biennially by the group of professional personnel required under paragraph (a)(2) of this section and updated as necessary by the CAH.

* * * * *

■ 48. Section 485.645 is amended by—
■ a. Revising paragraph (d)(1);
■ b. Removing paragraph (d)(4);
■ c. Redesignating paragraphs (d)(5) through (9) as paragraphs (d)(4) through (8), respectively; and
■ d. Revising newly redesignated paragraphs (d)(4) and (7).

The revisions read as follows:

§ 485.645 Special requirements for CAH providers of long-term care services ("swing-beds").

* * * * *

(d) * * *

(1) Resident rights (§ 483.10(b)(7), (c)(1), (c)(2)(iii), (c)(6), (d), (e)(2) and (4), (f)(4)(ii) and (iii), (g)(8) and (17), (g)(18) introductory text, and (h) of this chapter).

* * * * *

(4) Social services (§ 483.40(d) of this chapter).

* * * * *

(7) Dental services (§ 483.55(a)(2), (3), (4), and (5) and (b) of this chapter).

* * * * *

■ 49. Section 485.727 is amended by—
■ a. Revising paragraphs (a) introductory text, (a)(5), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);
■ b. Adding paragraph (d)(1)(v); and
■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 485.727 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The Organizations must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. The plan must do all of the following:

* * * * *

(5) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

* * * * *

(b) *Policies and procedures.* The Organizations must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and

updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The Organizations must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The Organizations must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the Organizations must conduct training on the updated policies and procedures.

(2) *Testing.* The Organizations must conduct exercises to test the emergency plan at least annually. The Organizations must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years. If the Organizations experience an actual natural or man-made emergency that requires activation of the emergency plan, the organization is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the Organization's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise their emergency plan, as needed.

* * * * *

■ 50. Section 485.914 is amended by revising paragraphs (d)(1) and (3) to read as follows:

§ 485.914 Condition of participation: Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client.

* * * * *

(d) * * *

(1) The CMHC must update each client's comprehensive assessment via the CMHC interdisciplinary treatment team, in consultation with the client's primary health care provider (if any), when changes in the client's status, responses to treatment, or goal achievement have occurred and in accordance with current standards of practice.

* * * * *

(3) For clients that receive PHP services, the assessment must be updated no less frequently than every 30 days.

* * * * *

■ 51. Section 485.920 is amended by revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, and (d) to read as follows:

§ 485.920 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The CMHC must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The CMHC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The CMHC must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The CMHC must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years. If the emergency preparedness policies and procedures are significantly updated, the CMHC must conduct training on the updated policies and procedures.

(1) *Training.* The CMHC must provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. The CMHC must demonstrate staff knowledge of emergency procedures. Thereafter, the CMHC must provide emergency preparedness training at least every 2 years.

(2) *Testing.* The CMHC must conduct exercises to test the emergency plan at least annually. The CMHC must:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based every 2 years. If the CMHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CMHC is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the CMHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CMHC's emergency plan, as needed.

* * * * *

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 52. The authority citation for part 486 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b–8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C 273).

■ 53. Section 486.104 is amended by revising paragraph (a) to read as follows:

§ 486.104 Condition for coverage: Qualifications, orientation and health of technical personnel.

* * * * *

(a) *Standard: qualifications of technologists.* All operators of the portable X-ray equipment meet the requirements of paragraph (a)(1) or (2) of this section.

(1) Successful completion of a program of formal training in X-ray technology at which the operator received appropriate training and demonstrated competence in the use of equipment and administration of portable x-ray procedures; or

(2) Successful completion of 24 full months of training and experience under the direct supervision of a physician who is certified in radiology or who possesses qualifications which are equivalent to those required for such certification.

* * * * *

■ 54. Section 486.106 is amended by revising paragraph (a)(2) to read as follows:

§ 486.106 Conditions for coverage: Referral for service and preservation of records.

* * * * *

(a) * * *

(2) Such physician or nonphysician practitioner's order meets the requirements at § 410.32 of this chapter, and includes a statement concerning the condition of the patient which indicates why portable X-ray services are necessary.

* * * * *

■ 55. Section 486.360 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);

■ b. Adding paragraph (d)(1)(v); and

■ c. Revising paragraph (d)(2)(i).

The revisions and addition read as follows:

§ 486.360 Condition for coverage: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The OPO must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The OPO must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and, the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The OPO must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The OPO must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the OPO must conduct training on the updated policies and procedures.

(2) * * *

(i) Conduct a paper-based, tabletop exercise or workshop at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. If the OPO experiences an actual natural or man-made emergency that requires activation of the emergency plan, the OPO is exempt from engaging in its next required testing exercise following the onset of the actual event.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 56. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102, 1128l, 1864, 1865, 1871 and 1875 of the Social Security Act, unless otherwise noted (42 U.S.C 1302, 1320a–7j, 1395aa, 1395bb, 1395hh and 1395ll).

§ 488.30 [Amended]

■ 57. Section 488.30(a) is amended in the definition for ''Provider of services, provider, or supplier'' by removing the phrase ''transplant centers'' and adding in its place the phrase ''transplant programs''.

■ 58. Section 488.61 is amended—

■ a. By revising the section heading;

■ b. In the introductory text by removing the phrase ''transplant centers'' and adding in its place the phrase ''transplant programs'';

■ c. In paragraph (a) by removing the phrases ''centers'' and ''center'' each time they appear and adding in their place the phrases ''programs'' and ''program,'' respectively;

■ d. In paragraph (a)(2) by removing the phrases ''Scientific Registry of Transplant Beneficiary (SRTR) center-specific'' and ''Scientific Registry of Transplant Recipient (SRTR) program-specific'' and adding in its place the phrase ''Scientific Registry of Transplant Recipient (SRTR) program-specific'';

■ e. By revising paragraph (a)(5);

■ f. By removing paragraph (c);

■ g. By redesignating paragraphs (d) through (h) as paragraphs (c) through (g), respectively;

■ h. By revising newly redesignated paragraphs (c), (d), (e) introductory text, (e)(1) introductory text, (e)(1)(iv), (e)(3), and (f)(1)(i), (ii), and (iii).

The revisions read as follows:

§ 488.61 Special procedures for approval and re-approval of organ transplant programs.

* * * * *

(a) * * *

(5) If CMS determines that a transplant program has met the data submission, clinical experience, and outcome requirements, CMS will review the program's compliance with the conditions of participation contained at §§ 482.72 through 482.76 and §§ 482.90 through 482.104 of this chapter using the procedures described in subpart A of this part. If the transplant program is found to be in compliance with all the conditions of participation at §§ 482.72 through 482.104 of this chapter, CMS will notify the transplant program in writing of the effective date of its Medicare-approval. CMS will notify the transplant program in writing if it is not Medicare-approved.

* * * * *

(c) *Loss of Medicare approval.* Programs that have lost their Medicare approval may seek re-entry into the Medicare program at any time. A program that has lost its Medicare approval must:

(1) Request initial approval using the procedures described in paragraph (a) of this section;

(2) Be in compliance with §§ 482.72 through 482.104 of this chapter at the time of the request for Medicare approval; and

(3) Submit a report to CMS documenting any changes or corrective actions taken by the program as a result of the loss of its Medicare approval status.

(d) *Transplant program inactivity.* A transplant program may remain inactive and retain its Medicare approval for a period not to exceed 12 months. A transplant program must notify CMS upon its voluntary inactivation as required by § 482.74(a)(3) of this chapter.

(e) *Consideration of mitigating factors in initial approval survey, certification, and enforcement actions for transplant programs*—(1) *Factors.* Except for situations of immediate jeopardy or deficiencies other than failure to meet requirements at § 482.80 of this chapter, CMS will consider such mitigating factors as may be appropriate in light of the nature of the deficiency and circumstances, including (but not limited to) the following, in making a decision of initial approval of a transplant program that does not meet the data submission, clinical experience, or outcome requirements:

* * * * *

(iv) Program improvements that substantially address root causes of graft failures or patient deaths, that have been implemented and institutionalized on a sustainable basis, and that are supported by outcomes more recent than the latest available SRTR report, for which there is a sufficient post-transplant patient and graft survival period and a sufficient number of transplants such that CMS finds that the program demonstrates present-day compliance with the requirements at § 482.80(c)(2)(ii)(C) of this chapter;

* * * * *

(3) *Timing.* Within 14 calendar days after CMS has issued formal written notice of a condition-level deficiency to the program, CMS must receive notification of the program's intent to seek mitigating factors approval, and receive all information for consideration of mitigating factors within 120 calendar days of the CMS written notification for a deficiency due to data submission, clinical experience or outcomes at § 482.80 of this chapter. Failure to meet these timeframes may be the basis for denial of mitigating factors. CMS may permit an extension of the timeline for good cause, such as a declared public health emergency.

(f) * * *

(1) * * *

(i) Approve initial approval of a program's Medicare participation based upon approval of mitigating factors.

(ii) Deny the program's request for Medicare approval based on mitigating factors.

(iii) Offer a time-limited Systems Improvement Agreement, in accordance with paragraph (g) of this section, when a transplant program has waived its appeal rights, has implemented substantial program improvements that address root causes and are institutionally supported by the hospital's governing body on a sustainable basis, and has requested more time to design or implement additional improvements or demonstrate compliance with CMS outcome requirements. Upon completion of the Systems Improvement Agreement or a CMS finding that the hospital has failed to meet the terms of the Agreement, CMS makes a final determination of whether to approve or deny a program's request for Medicare approval based on mitigating factors. A Systems Improvement Agreement follows the process specified in paragraph (g) of this section.

* * * * *

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

■ 59. The authority citation for part 491 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 60. Section 491.9 is amended by revising paragraph (b)(4) to read as follows:

§ 491.9 Provision of services.

* * * * *

(b) * * *

(4) These policies are reviewed at least biennially by the group of professional personnel required under paragraph (b)(2) of this section and reviewed as necessary by the RHC or FQHC.

* * * * *

■ 61. Section 491.11 is amended by revising paragraph (a) to read as follows:

§ 491.11 Program evaluation.

(a) The clinic or center carries out, or arranges for, a biennial evaluation of its total program.

* * * * *

■ 62. Section 491.12 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);

■ b. Adding paragraph (d)(1)(v); and

■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 491.12 Emergency preparedness.

* * * * *

(a) *Emergency plan.* The RHC or FQHC must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The RHC or FQHC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The RHC or FQHC must develop and maintain an emergency preparedness communication plan that complies with

Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The RHC or FQHC must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the RHC/FQHC must conduct training on the updated policies and procedures.

(2) *Testing.* The RHC or FQHC must conduct exercises to test the emergency plan at least annually. The RHC or FQHC must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years. If the RHC or FQHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the RHC or FQHC is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the RHC or FQHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the RHC or FQHC's emergency plan, as needed.

* * * * *

PART 494—CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

■ 63. The authority citation for part 494 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. l302 and l395hh).

■ 64. Section 494.62 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);

■ b. Adding paragraph (d)(1)(vii); and

■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 494.62 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The dialysis facility must develop and maintain an emergency preparedness plan that must be evaluated and updated at least every 2 years. The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation. The dialysis facility must contact the local emergency preparedness agency at least annually to confirm that the agency is aware of the dialysis facility's needs in the event of an emergency.

(b) *Policies and procedures.* The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The dialysis facility must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training, testing, and orientation.* The dialysis facility must develop and maintain an emergency preparedness training, testing and patient orientation program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training, testing, and patient orientation program must be evaluated and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(vii) If the emergency preparedness policies and procedures are significantly updated, the dialysis facility must conduct training on the updated policies and procedures.

(2) *Testing.* The dialysis facility must conduct exercises to test the emergency plan at least annually. The dialysis facility must do all of the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, a facility-based functional exercise every 2 years. If the dialysis facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ESRD is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the dialysis facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the dialysis facility's emergency plan, as needed.

* * * * *

Dated: August 6, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: August 9, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–19599 Filed 9–17–18; 11:15 am]

BILLING CODE 4120–01–P