Regulatory/Statutory Considerations

HHS/CMS should institute the following policies where it is within their authority and support statutory modifications where necessary to reduce exposure risks of patients and clinicians and to increase availability of clinicians for patient care rather than paperwork.

	HOME HEALTH	ILEGISLATIVE	
Statute or Regulation	Outcome sought	Rationale	Status
1814(a)(2); 42 CFR 409. 42(a)	Establish a "homebound" interpretation to consider individuals suspected of infection and those that need intermittent skilled care who are at increased risk in using outpatient services to meet the "homebound" requirement for benefit eligibility. Presumptive eligibility for all individuals over age 60 a sit is medically contra-indicated to leave the home during the pandemic.	Patients who are suspected or confirmed to have COVID-19 along with other Medicare beneficiaries of advanced age may not physically meet the homebound standard even though they are instructed to self-isolate in their home. However, CDC and other guidance firmly states that these individuals should self- isolate and not venture into the open community as they are at high risk. As such, it is "medically contra- indicated" that they leave their homes. That is an existing standard for homebound status.	COMPLETED
1814(a)(2)(C)	Medicare face-to-face physician encounter requirements for home health—permit telephonic encounters as an alternative to direct physician contact.	The face-to-face physician encounter may be conducted by telehealth but not telephonically. Many home health patients do not have access to or use sophisticated technologies, and therefore will need to leave their home to see a physician.	NEARLY COMPLETED Need to permit audio telephonic communications as an acceptable medium
1814(a)(2)(C)	Allow NPs and PAs to	Under current statute,	Congress passed

	contifue for alightility and	only on hypician mary	logislation to
	certify for eligibility and	only a physician may	legislation to
	order home health services	certify patients for	permit NPs, PAs,
	where permitted by the state.	Medicare for home	and CNSs to certify
		health services and write	an order home
		orders patients served by	health (as permitted
		the Medicare certified	under state scope of
		agency. NP and PAs are	practice).
		increasingly serving as	
		the primary practitioner	CMS accelerated
		for patients, particularly	implementation
		in rural areas. HHAs	through non
		must locate a physician	enforcement policy
		that is willing to oversee	issuance.
		the patient care when	
		the primary practitioner	REQUESTING:
		for a patient is an NP or	Accelerate formal
		PA	regulation to
			implement CARES
			provision
1814(a)(2)(C)	Allow beneficiaries to	The Act specifically	Requested
and	qualify for home health	excludes venipuncture	
1835(a)(2)(A)	services on the sole basis for	as a sole basis for	
	needed venipunctures.	qualifying for Medicare	
		home health services.	
		Physicians are	
		requesting HHAs to	
		perform venipunctures	
		for beneficiaries unable	
		to leave the home due to	
		the pandemic. These beneficiaries required	
		monitoring related to	
		clinical conditions and	
		/or to monitor drug	
		levels, such as PT/INR,	
		digoxin, thyroid, etc.	
	HOME HEALTH	, ,	
	Payn		
§484.205(g)(1)	Restore RAP payment to	Under PDGM RAP	REQUESTED
	60% of payment for initial	payment were decreased	
	60% of payment for initial 30day periods and 50% for	to 20% for all 30 day	
	30day periods and 50% for	to 20% for all 30 day	
	30day periods and 50% for	to 20% for all 30 day periods. Increasing RAP	
	30day periods and 50% for subsequent 30 day periods	to 20% for all 30 day periods. Increasing RAP payments will provide	

		operations.	
§484.205(a)	Suspend the 2020 4.36%	Suspending the	REQUESTED
	behavior adjustment and the	adjustment would infuse	
	annual Productivity	some financial support	
	adjustment in the current	to HHAs while they are	
	payment system (PDGM)	experiencing vast	
		changes in the makeup	
	PAYMENT PRIORITY #1	of the patients served	
		(including Covid-19	
		patients), increased costs	
		for infection controls	
		and emergency actions,	
		staffing costs as	
		caregivers face	
		infections, and many	
		other complications not	
		built into the PDGM	
		system. It is appropriate	
		because both 2020	
		behavior and	
		productivity has been	
		turned inside out. The	
		failsafe in suspending	
		the adjustment is that	
		the law includes a	
		reconciliation authority	
		to ensure budget	
		neutrality.	
§484.220(a)	Permit agencies to receive	Symptom codes such as	REQUESTING
	reimbursement when the	Z03.818 and Z20.828	
	primary diagnosis is a	are unacceptable	
	contact/exposure code (such	primary diagnosis codes	
	as Z20.828 or Z03.818)	for home health claims	
		and are not grouped in	
		the PDGM payment	
		model. HHAs cannot be	
		reimbursed for care	
		provided to PUI for	
S 400 43()		COVID-19	DEQUERTED
§409.43(c)	Waive or suspend the	Physicians are	REQUESTED
	requirements that HHAs	unavailable to sign	
	have signed and dated	orders during the	
	physician certifications and	emergency. Verbal	
	care orders prior to billing.	orders should be	
		sufficient to bill	
	PAYMENT PRIORITY #2	Medicare.	

§409.46(e)	Permit physician-ordered telehealth and remote monitoring visits to count as Medicare home health visits.	In order to continue care for patients while maintaining social distancing, HHAs are planning on using telehealth services and remote monitoring in lieu of visits. In addition, patients are refusing to permit HHA staff into their home due to the COVID 19 outbreak. Telehealth and remote monitoring visits by HHAs are not reimbursable under the Medicare program and will cause significant financial hardship for both the agency and the staff.	CMS did not allow for telehealth reimbursement or credit as visit equivalency
	HOME HEALT	HCOVERAGE	
	POL		
Pub. 100.2, chapter 10, 40.1.3	Provide flexibility in the definition of "intermittent skilled nursing" to permit a one-time skilled nursing visit for specified interventions, such as, injections that would ordinarily be provided during a physician's office visit.	The Act at 1861(defines intermittent, for the purposes of §§1814(a)(2) and 1835(a)(2)(A), as skilled nursing care that is either provided or needed on fewer than 7 days each week, or less than 8 hours each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable.) However. CMS policy includes a requirement that the patient must have a medically predictable <u>recurring</u>	REQUESTED

			I
		need for skilled nursing	
		services, which prohibits	
		a physician from	
		ordering one-time home	
		health skilled nursing	
		visits.	
	Demonstration		
CMS	Suspend expansion of the	The RCD is a very	RCD suspended
Demonstration	Review Choice	resource intensive	
Program	Demonstration (RCD)	medical review process	However, CMS
	project	that requires HHAs to	will have MACs do
		submit the entire	100% post-pay
	DEMO PRIORITY #1	medical record to the	review
		Medicare claims	
		processing contractor	REQUESTING:
		before payment can	
		made on the claim. In	Suspension of post-
		states where the	pay review as it
		demonstration is being	adds burden and
		conducted, a HHA's	increases HHA risk
		ability to respond to the	
		COVID-19 pandemic	Extension of RCD
		would be significantly	review choice
		limited	selection deadline
		mmuu	until an
			announcement as to
CMS-CPI	Suspend Targeted Probe and	TPE is not focused on	the new start date. COMPLETED
UND-UI 1	Educate audits	parties suspected of	
		fraud and abuse. Current	
		"improper payment rate" is at an all-time	
		low. TPE management	
		requires HHA staff to	
		focus on paperwork, not	
	T /'/ / NT /' 1	patient care.	DEOLIEGEDIG
CMS/OHA	Institute National	Providers of all types	REQUESTING
	Accelerated Appeals	have pending Medicare	
	Settlements	appeals. Past settlement	
		efforts proved beneficial	
		to Medicare and	
		appellants in terms of	
		efficiencies. The PHE	
		justifies broad-scale	
1		settlements to reduce	

		burdens on all	
		stakeholders	
CMMI	Suspend the HHVBP demo	We are very supportive	REQUESTING
	Suspend the Iniviti demo	of the HHVBP demo.	REQUESTING
		However, there has been	
		a massive change in	
		case mix and clinical	
		practice while	
		addressing the	
		pandemic. As a	
		performance year, 2020	
		would not be a good	
		time to learn about how	
		financial incentives and	
		penalties impact patient	
		outcomes	
	HOME HEALTH		
-	Conditions of		
§484.80(h)	Supervision of home health	Telephonic/telehealth	COMPLETED
	Aides.	supervision of home	
	Agencies must make an on-	health aides for home	
	site visit every 14 days to	health agencies to	
	supervise the home health	extend the availability of	
	services	clinical staff and	
		promote social	
		distancing while	
		maintaining home care aide oversight should be	
		sufficient in the	
		emergency period. It	
		reduces PPE need and	
		expands clinical service	
		time availability.	
		time uvunuomity.	
§484.80(c)	Streamline home care aide	Several of the	REQUESTED
0	competency evaluations to	competency	
	include only those	requirements could be	
	competencies required for	waived during the	
	direct patient care.	pandemic to permit	
	-	additional personnel be	
		trained as home care	
		aides	
§484.80(d)	Waive the 12-hour annual in-	Will help address	REQUESTED
-	service training requirement	staffing shortages and	
	for home health aides	address need to focus	
		efforts on patient care	

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§484.55(a)	Permit HHAs to conduct the initial evaluation visit using telehealth and medical record review.	The initial evaluation assesses for beneficiary eligibility and immediate care needs which could appropriately be evaluated via telehealth and medical record review fostering efficient use of resources when	COMPLETED
§484. 55(c)	Permit agencies to conduct an abbreviated comprehensive assessment, which includes the OASIS items, to include only items needed for care planning and payment. Home Health COP PRIORITY #1	evaluating referrals Many of the items in the assessment are required to be collected by the conditions of participation, but not required for payment or care planning. An abbreviated assessment will free up valuable clinician time that can be dedicated to patient care during a pandemic. CMS has approved such in the past emergencies.	REQUESTED
§484.55(b)	Allow for Flexibility Regarding Comprehensive Assessments completion time frame	The conditions of participation require that the extensive comprehensive assessment must be completed within 5 days of the admission to the HHA. Adhering to tight time frames for the assessment completion misappropriates needed resources during a pandemic. Resources should be dedicated to patient care and not administrative activities to meet regulatory requirements.	COMPLETED

§484.55(a) and (b)	Permit a therapist to conduct the initial visit and comprehensive assessment when both therapy and nursing are ordered at the start of care.	Therapists are not permitted to conduct the initial evaluation visit and comprehensive assessment when nursing services are also ordered. There is no clinical rationale for the requirement and it wastes valuable staff resources.	REQUESTED
§484.55(d)	Permit home health agencies to perform telephonic or telehealth OASIS recertification assessment visits on homebound patients that have a continued skilled need and are refusing visits due to fear of exposure.	This will allow the home health agency to continue monitoring the patient condition to assure no decline, potentially avoiding a hospitalization. Otherwise the HHA must be discharge the patient from the agency at the end of the 60 day episode.	REQUESTED
§484.60(c)	Waive the requirement for written information to be provided to the patient at admission and allow HHAs to verbally inform the patient of the required information under this standard.	Information, such as, a medication list, all services and treatments listed on the plan of care, and visit schedules must be provided to the patient in writing on admission to the agency, and updated whenever changes occur. Limiting the amount of written information that must be provided to patients on admission will allow clinicians more time for direct patient care.	REQUESTED
§484.105(f)	Waive the one service directly requirement for home health agencies to meet increased, but temporary service demand	Under the one service directly rule at least "one discipline" in its entirety must be provided by a W2	REQUESTED

		amplouse of the same-	
		employee of the agency. Staffing shortages that might occur during the COVID-19 pandemic could require that home	
		health agencies contract for all disciplines.	
§484.100(c)	Relief from restrictions under the Clinical Laboratories Improvement Act to permit home health and hospice personnel to collect, transport, conduct, and report COVID-19 test results	HHAs must have a designated laboratory and meet CLIA standards in order conduct laboratory tests unless the test is a CLIA waived test. As the pandemic progresses HHAs will be well positioned to collect, transport, conduct and report laboratory tests related to COVID-19.	REQUESTED
42 CFR Part 484	Delay OASIS-E	While OASIS-E is not scheduled to start until 2021, much work will need to be done by HHAs on their contractors to prepare for it in 2020.	REQUESTING
	HOSPICE LE	GISLATIVE	
Statute or Regulation	Outcome sought	Rationale	Status
1814(a)(7)(D)(i)	Permit use of telehealth technologies to fulfill the hospice face-to-face requirement, including telephonic audio communications	Allow confirmation of continuing eligibility for hospice care and address staffing shortages; limit threat of virus spread	PARTIALLY COMPLETED REQUESTING: extend to telephone audio and record review as options
1814(a)(7)(D)(i)	Allow physician assistants (PAs) to conduct the hospice face-to-face encounter Expanded 1135 Waiver Authority PRIORITY #1	PAs may serve as hospice attending physicians; allowing them to conduct the face-to-face will ease demands on physicians and allow timely	REQUESTING

		compliance with requirement	
		requirement	
1814(a)	Allow PAs and NPs to certify hospice eligibility EXPANDED 1135 Waiver Authority PRIORITY #2	Allows PAs and NPs to perform up to full scope of practice and will ease burdens on hospice physicians	REQUESTING
	HOSPICE RE	GULATORY	
1135	Expand telehealth waivers to include hospice visits on the plan of care and for assessment purposes; permit use of various technologies, including audio-only telephonic interactions, as needed based on technology available to patient. Permit inclusion of telehealth visits on the claim Hospice Regulatory PRIORITY #1	Limit the spread of the virus, address growing concerns among seniors around admitting individuals into their homes, address difficulties in accessing patients in nursing homes and other facilities, maximize use of staff	CMS issued clarification; permits telecommunication- based visits as ordered on plan of care without reimbursement effect REQUESTING: Expand telehealth allowance to include GIP and respite care when needed for consultations between hospice staff and patient'facilty.
1135	Allow hospice physician services conducted via telehealth to be billed as regular physician services, comparable to community physicians	Address staffing limitations, expanded patient care needs and limits potential virus spread	PARTIALLY COMPLETED; CMS allows hospice to bill medical services by hospice physicians and NPs serving as attending physician; must meet "telehealth" standard
§418.64	Allow contracting for core services (nursing, medical social services, counseling)	Address staffing shortages and increased patient care needs	REQUESTED
§418.72	Waive non-core services requirement during national emergency	Allows hospices to not provide PT, OT, speech- language to reduce	CMS initiated; COMPLETED

		exposure	
§ 418.54(a), 418.54(d), 418.56(d)	Allow for flexibility regarding time frame for completion of initial and comprehensive assessments, and updates to the comprehensive assessment and review of the plan of care (currently every 15 days) Hospice COP PRIORITY #2	Ability to deliver patient visits is being limited as patients are fearful of potential risk; this will allow for those circumstances where a full initial or comprehensive assessment (or routine reassessment) may not be completed within time frames specified in regulation; will help align safety/care requirements with ability of hospice staff to make necessary in- person visits	Partially addressed; timeframes for updates to assessments extended to up to 21 days REQUESTING: Timeline extension on initial and comprehensive assessments
\$418.204, 418.108, 418. 302	Allow for flexibilities related to use of General Inpatient Care (GIP), Continuous Home Care (CHC), and Inpatient Respite Care to address circumstances under which patients may not be admitted to nursing homes (due to lockdowns) or require more intensive care from hospice due to caregiver illness; allow respite care to be provided in the home. Ease CHC to allow hospices to determine care needs (reduce minimum hour requirements, allow for different staffing ratio, allow CHC to be calculated using any 24-hour period). Waive 5-day limit for respite care.	Helps address growing challenges regarding care transitions, need for additional care when family caregiver is ill, reduced availability of inpatient and respite beds in facilities and allows patients to meet eligibility requirements given special pandemic circumstances	REQUESTED
§418.76(h)	Permit telephonic/telehealth supervision of hospice aides and LPNs/LVNs to meet supervision requirements where appropriate	Will help address RN shortages and limit risk of patient exposure during pandemic	COMPLETED; CMS waived requirement

§418.76(c)(1)	As part of hospice aide competency evaluation, allow hospices to use pseudo patients for competency testing of aides for tasks that must be observed on patient; allow "qualified hospice aides" to include those who are competency tested only in the areas/tasks for which they will be assigned	Will help address staffing shortages and exposure of patients to risk	REQUESTED
§418.76(d)	Waive the 12-hour annual in- service training requirement for hospice aides	Will help address staffing shortages and address need to focus efforts on patient care	REQUESTED
§418.78(e)	Waive the 5% level of activity requirement for hospice volunteers	Many hospice volunteers are elderly and/or have health conditions; this will help reduce exposure of these individuals (and patients); will also address current limitations on hospice worker entry to nursing homes and assisted living facilities	COMPLETED
§418.56(d)	Align timeframe for review of the plan of care with the extended timeframe for the comprehensive assessment	Updated comprehensive assessments drive the plan of care so hospices typically review the plan of care along with completing the updates to the comprehensive assessments.	REQUESTING
\$418.24(a)(2); 418.26	Provide flexibility on 5-day timely filing requirement for NOE/NOTR	Ease staffing burdens and allow staff to focus on essential needs related to patient care	REQUESTED
CMS-CPI	Suspend Targeted Probe & Educate Audits	TPE is not focused on parties suspected of fraud and abuse. Current "improper payment rate"	COMPLETED

418.24(b)(8)	Allow verbal election of the Medicare Hospice Benefit in circumstances where the patient is unable to make his/her own decisions and the legal representative cannot be available to sign the statement due to the pandemic/is not able to utilize alternative methods of delivery of a signed election statement (i.e. mail, FAX, etc.)	is at an all-time low. TPE management requires hospice staff to focus on paperwork, not patient care. When the legal representative is not available and cannot leave the home for alternative delivery methods (i.e. cannot go to public FAX location, cannot go to post office, etc.), verbal election allows the patient to be admitted to hospice care and begin receiving services immediately.	REQUESTED
§418.116(b) Standard: Laboratory services	Relief from restrictions under the Clinical Laboratories Improvement Act to permit home health and hospice personnel to collect, transport, conduct, and report COVID-19 test results	HHAs must have a designated laboratory and meet CLIA standards in order conduct laboratory tests unless the test is a CLIA waived test. As the pandemic progresses HHAs will be well positioned to collect, transport, conduct and report laboratory tests related to COVID-19.	REQUESTED
MEDICAID 484.55(h)(2)	60-day aide supervisory visit	Allows waiver of 60-day aide supervisory visit when patient is only receiving personal care services	REQUESTED