

March 16, 2020

Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) asks **the Secretary of Health and Human Services (HHS) to consider additional actions to temporarily suspend certain requirements in order for health care providers to better respond to the novel coronavirus (COVID-19) outbreak.**

On Jan. 31, 2020, your office declared a public health emergency in the U.S. for COVID-19, representing an important first step in combatting this virus. The public health emergency together with the President's recent national emergency declaration enabled your office to make several critical waivers consistent with section 1135 of the Social Security Act. We appreciate your swift action in making these waivers, including removing the critical access hospitals (CAH) limitation of 25 inpatient beds and 96-hour average length of stay, the long-term care hospital (LTCH) 25-day length of stay requirement, the inpatient rehabilitation facility (IRF) 60% Rule, and certain physician licensing requirements. However, much more flexibility is required to allow hospitals and health systems to most effectively respond to this emergency and provide the best care possible to patients. For example, we ask you to:

1. Waive the CAH 96-hour condition of payment in addition to the 96-hour average length of stay. This is crucial for rural areas that may not have other options for inpatient beds.
2. Waive the requirement that an LTCH patient have a prior hospital stay that includes three or more days in the intensive care unit (ICU) in order to qualify for the full payment rate. Doing so would help ensure these hospitals are able to add capacity to the health care system by caring for more appropriate patients, without penalty.



3. Waive the IRF 3-hour rule, which requires that IRF patients receive at least three hours of therapy a day, the “preponderance” of which must be one-on-one. This is critical to enabling them to add capacity to the health care system.

A list of our specific suggested actions are attached.

Other important waiver flexibilities that we urge you to consider cover conditions of participation or other certification requirements, program participation, preapproval requirements and performance deadlines and timetable delays. The HHS Secretary should also immediately implement unique codes for COVID-19 disease, exposure to COVID-19 and screening for the virus. Such codes are essential to tracking COVID-19 patients or patients without the disease that require health care services. While there are codes existing for coronaviruses, they are not unique to COVID-19. For all waivers, including those already made, the HHS Secretary should also consider creating a code for providers to use to identify patients *without* COVID-19 who are receiving care under a waiver – those who are, for example, transferred to a post-acute care hospital solely in order to meet the demands of the emergency. This is much less resource intensive than documentation in the medical record.

In addition, while a number of actions require the use of section 1135 waiver authority, there also are additional steps that HHS can take without such authority. For example, we encourage the agency to require that health plans reduce access barriers, such as limiting utilization management techniques that could delay access to COVID-19 testing and treatment, and require that coverage decisions be based on presenting symptoms, not final diagnosis.

Finally, we must acknowledge and accept the unknowns we face when combatting COVID-19. Our requests today represent actions we know are necessary at this moment. If taken, these steps will help care for patients, while keeping hospital workers and the public as safe as possible. As more information becomes available, we anticipate the need for additional assistance from HHS, and ask that the agency remain flexible as our hospitals and health systems continue to care for patients during this national emergency.

Communities rely on America’s hospitals and health systems to be there for them in the face of an emergency. Whether that emergency develops in the form of a natural disaster, like a hurricane or tornado, or as a virus, like COVID-19, hospitals and health systems are prepared to fulfill their commitment to patients. While our members continue to do everything they can to address COVID-19 cases, the additional action we request would help them continue to put the health and safety of patients first by removing barriers that threaten to impede decisive and quick action by providers at a time when agility and flexibility are of utmost importance.

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We appreciate your leadership and the ongoing work of the White House Coronavirus Task Force. We look forward to continuing to work with you during this critical time to protect the health of our nation.

Sincerely,

/s/

Richard J. Pollack
President and Chief Executive Officer

Cc: Seema Verma, Administrator, Centers for Medicare & Medicaid Services
Stephen M. Hahn, M.D., Commissioner, Food and Drug Administration
Robert R. Redfield, M.D., Director, Centers for Disease Control and Prevention

ASSISTANCE MANAGING THE SURGE

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| <p>Medicare Outpatient Observation Notice (MOON). In addition to the Centers for Medicare & Medicaid Services' (CMS) waiver of the skilled nursing facility (SNF) 3-day rule, waiving the MOON written and oral notification requirements is appropriate since undergoing observation care will have no implications for SNF eligibility.</p> |
| <p>Home Health (HH) Homebound Requirement. Waiving the requirement that a beneficiary must be "home-bound" in order to receive HH services would allow beneficiaries to obtain care while minimizing the risk to themselves or others.</p> |
| <p>Critical Access Hospital (CAH) 96-hour Condition of Payment. Waiving the requirement that a physician certify a patient can reasonably be expected to be discharged within 96 hours would provide critical flexibility for care in rural areas that may not have other options for inpatient care.</p> |
| <p>Medical Review Audits. Pausing all audits during the emergency, including additional documentation requests and other audit work, would help free capacity in the health care system.</p> |
| <p>HH Face-to-Face Requirement. Waiving the requirement that the certifying physician or nonphysician practitioner document a face-to-face encounter with the patient prior to certifying a patient's eligibility for the HH benefit would allow beneficiaries to obtain care while minimizing the risk to themselves or others. In these situations, a telephonic or telehealth visit may fulfill the requirements of the face-to-face requirement.</p> |
| <p>Transfer of Mechanically Ventilated Patients. Suspending the restrictions of Medicare Managed Care organizations surrounding transfer of mechanically ventilated patients to long-term care hospitals (LTCHs) would allow patients to be transferred as soon as they are physiologically stable enough. This would facilitate appropriate transfer of patients that benefit from the specialized care LTCHs provide and also add capacity to the health care system.</p> |
| <p>Federal Audits. Delaying all federal audits during the emergency, such as Medicaid disproportionate share hospital (DSH) and Payment Error Rate Measurement (PERM), would help free capacity in the health care system.</p> |
| <p>Waiving certain CMS certification requirements. If a nonprofit entity that holds multiple certificates to operate hospitals in that jurisdiction from the appropriate state licensing entity, a certificate of participation from CMS, a license from a state licensing authority to operate a new or refurbished hospital and has applied for accreditation to operate a new or refurbished hospital that facility may be deemed certified for billing by CMS and private insurance entities. The nonprofit entity would receive certification for no more than 90 days or until accreditation is received or the national emergency has ended. Entities may renew this temporary certification every 90 days for up to one year.</p> |
| <p>Physical Environment. Waiving physical environment requirements at 482.41; would allow non-hospital buildings and spaces to be used for patient care, provided sufficient safety and comfort is provided for patients and staff, thus adding capacity to the health care system.</p> |

HH Review Choice Demonstration. Suspend expansion of the HH Review Choice Demonstration project to allow clinical staff to focus on accommodating coronavirus patients and those transferred to home health due to the disaster. Also, suspend ongoing demonstration activities in Illinois, Ohio and Texas.

ENSURING STAFF CAN FOCUS ON CARE DELIVERY

Additional EMTALA Sanctions Waiver. In addition to waivers issued on March 15, 2020, waiving the following EMTALA sanction would assist hospitals in most effectively managing patient care and health care system capacity:

1. Permit the medical screening examination to be conducted by other qualified staff authorized by the hospital and acting within their state scope of practice and licensure, who are not formally designated to perform medical screening examinations in the hospital by-laws or in the rules and regulations.

Practice Limitations. Waiving specific practice limitations on nurse practitioners that are more restrictive under CMS than under state licensure would help address workforce shortages.

Waiving standard death reporting requirements at 482.13(g), which would allow the reporting of the death of patients who were in seclusion or restraint to occur later than currently required. This would keep the requirement where any death where restraint may have contributed is reported within standard time limits.

Medical Record Timing. Waiving medical records timing requirements at 482.24 would allow medical records to be fully completed later than 30 days following discharge, providing flexibility to the health care system.

Verbal Orders. Waiving verbal order requirements at 482.24 would allow verbal orders to be used more frequently and authentication may occur later than 48 hours, thus providing flexibility to the health care system.

Physician Privileging. Waiving certain physician privileging requirements at 482.22(a) would allow physicians whose privileges will expire and new physicians to begin practice before full medical staff/governing body review and approval, adding capacity to the health care system.

Discharge Planning Requirements. Waiving hospital discharge planning requirements that prohibit hospitals from specifying or otherwise limiting the information provided on post-hospital services is necessary because the capacity and/or capabilities of available facilities to care for COVID-19 patients may be severely limited, effectively restricting patient choice, and this is a time consuming task that draws nurses away from direct patient care.

HH Assessments. Waiving HH requirements at 484.55 would remove a series of requirements around initial and comprehensive assessments. For example, it would allow HH agencies to perform initial assessments and determine patients' homebound status remotely or by record review, so that beneficiaries can obtain care while minimizing the risk to themselves or others. It also would grant greater flexibility with the timing of and information included in patient assessments.

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| <p>Expanded Use of Telehealth. Insurers should support management of scarce resources, such as personal protective equipment, and efforts to reduce community transmission by expanding access to services delivered via telehealth.</p> |
| <p>Credentialing. Requiring expedited or presumptive credentialing, such as requiring health plans to establish a process to recognize and credential community physicians who offer to work at hospitals and health systems, would help to ease workforce shortages during this time.</p> |
| <p>Patient Assessments. Granting relief to all providers on the timeframes related to pre- and post-admission patient assessment and evaluation criteria would help ensure patients are treated in a timely manner.</p> |
| <p>CMS Survey of 340B Hospitals. CMS should suspend its scheduled survey of all hospitals that participate in the 340B Drug Pricing Program collecting actual acquisition costs for specified covered outpatient drugs (SCODs). While AHA has significant issues with the survey design, our paramount concern is the significant reporting burden this survey would place on 340B hospitals during the COVID-19 national health emergency.</p> |
| <p>Administrative Timeframes. Allowing leniency in administrative timeframes, including for billing and the submission of Medicare Cost Reports, for hospitals/health systems that experience business disruptions, e.g., as a result of workforce shortages.</p> |

HELP US GET THE TOOLS WE NEED

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| <p>Sterile Compounding. Waiving sterile compounding requirements at 482.25(b)(1) and USP 797 would allow face masks to be removed and retained in the compounding area to be re-donned and reused during the same work shift only to conserve scarce face mask supplies.</p> |
| <p>340B Eligibility. Providing for a limited waiver of the 340B Hospital Medicare DSH eligibility threshold for current 340B hospitals responding to the COVID-19 national health emergency and experiencing a significant change in patient mix would help ensure that hospitals do not lose their 340B status in the future as a result of a time-limited change in patient mix.</p> |
| <p>Prior Authorization for Post-acute Care (PAC). Requiring that plans waive prior authorization requirements for PAC placement would enable hospitals to free up inpatient bed capacity.</p> |
| <p>Restrictions on Telehealth Technology. Waive the restrictions on the type of technology that may be used to provide telehealth would allow patients to use the technology they have on hand, such as FaceTime and Skype, providing critical flexibility that will allow them to remain in their homes while still obtaining services. These waivers must be made in conjunction with those above on geographic and originating sites and below on HIPAA privacy requirements in order to be meaningful.</p> |
| <p>HIPAA Privacy Requirements. Waiving HIPAA privacy requirements and permitting a similar waiver of applicable security rule requirements would allow patients to use technologies such as FaceTime and Skype, as specified above. These waivers must be made in conjunction with those above on geographic and originating sites and telehealth technology in order to be meaningful.</p> |

IRF 3-hour Rule. Waiver of the 3-hour rule, which requires that inpatient rehabilitation facility (IRF) patients receive at least three hours of therapy a day, the “preponderance” of which must be one-on-one, would help ensure that IRFs are able to add capacity to the health care system, without penalty.

LTCH 50% Rule. Waiving both the numerator and denominator of the requirement that LTCHs have no more than 50% of Medicare cases paid at the site-neutral rate would help ensure they are able to add capacity to the health care system by caring for appropriate patients, without penalty.

Emergency Use Authorizations (EUAs). Expediting the approval of EUAs for hospital laboratory developed tests (LDTs), including the approval of licensed automated testing systems and rapid response testing, would assist hospitals in expeditiously testing and confirming COVID-19 infection in patients and thus responding to the emergency.

Access to Coronavirus. Access to the virus and its genomic RNA would allow hospitals to validate their LDTs. Some hospitals with laboratories certified for high complexity testing under CLIA are having difficulty obtaining this material

ENSURE COVERAGE SO ALL PATIENTS CAN SEEK HELP WHEN NECESSARY

Presumptive Authorization. Requiring plans to accept presumptive authorization in instances where health plans, due to business disruption such as reduced workforce capacity, cannot adjudicate requests within a timely manner, would help ensure patients are treated in a timely manner.

Presenting Symptoms as Basis for Coverage. Generally, insurers make coverage decisions in part by assessing whether care was medically necessary, and many insurers adjudicate medical necessity using information that becomes available during the course of treatment or testing. This approach could result in many coverage denials for individuals who were originally suspected to have coronavirus but who ultimately are found to have the flu. The government should clarify that coverage decisions must be made on the presenting symptoms, not the final diagnosis.

Cost-sharing. Mandating that all forms of cost-sharing (co-pays, co-insurance, deductibles) be waived not only for testing, but also for treatment of coronavirus would help eliminate cost as a barrier to care. CMS should also require plans to reimburse providers for the full contracted amount.

Out-of-network Care. We urge the government to direct health plans to hold the patient harmless for out-of-network care, such as laboratory services, and negotiate reimbursement with the provider.

Utilization Management Requirements. Requiring health plans to ease utilization management requirements during the emergency period to account for reduced workforce would help ensure there are not bottlenecks and unnecessary delays in care. Specifically, hospitals and health systems are expected to experience staff reductions and diversions and health plans should not be permitted to deny reimbursement for care for which providers were unable to complete prior authorization or other utilization management functions due solely to workforce constraints.

Ensuring Adequate Coverage and Resources. Refraining from implementing policies that would reduce Medicaid coverage and/or resources would help ensure patients get the care they need. Specifically, we ask that the Administration withdraw the proposed Medicaid Fiscal Accountability Rule, which could have a negative impact on coverage and health care system resources just as we seek to manage COVID-19 patients.

Automatic Eligibility Renewal. Allowing states six month automatic eligibility renewal would help ensure continuity of coverage.

Increase Access to Presumptive Eligibility. The Administration should remove administrative barriers to Medicaid hospital presumptive eligibility during the COVID-19 emergency to increase access to coverage.

Children's Health Insurance Program (CHIP) Eligibility Limits. Federal law restricts states from increasing their CHIP eligibility limits. We urge flexibility to states seeking to expand CHIP eligibility within their current CHIP grants to enable access to testing and treatment for uninsured children.

Uncompensated Care Pools. Allow states to reestablish or create time-limited Medicaid-funded uncompensated care pools through Medicaid Section 1115 demonstration waivers to cover the costs of the uninsured.

Special Enrollment Period. Creating a special period enrollment for the Health Insurance Marketplaces would increase access to coverage and care.

Direct Provider Reimbursement. Establishing a federal program to directly reimburse providers for costs associated with caring for the uninsured would help ensure hospital have adequate resources for addressing the emergency. While federal law now provides a mechanism for reimbursement for testing and testing-related services, this must be expanded to treatment costs as well.

Medicaid DSH. Delaying Medicaid DSH cuts and establishing a temporary Medicaid DSH allotment increase would help cover COVID-19 related testing and treatment, including equipment.

ENSURE PAYMENT FLOWS APPROPRIATELY

Telehealth Geographic and Originating Site Requirements. Waiving the geographic site requirements that limit telehealth payment to services furnished within certain geographic areas, as well as the originating site requirements that specify the particular sites at which the eligible telehealth individual must be located would provide critical flexibility to allow patients to remain in their homes while still obtaining services. These waivers must be made in conjunction with those below on telehealth technology and HIPAA privacy requirements in order to be meaningful.

LTCH 50% Rule. Waiving both the numerator and denominator of the requirement that LTCHs have no more than 50% of Medicare cases paid at the site-neutral rate would help ensure they are able to add capacity to the health care system by caring for appropriate patients, without penalty.

LTCH ICU Requirement. Waiving the requirement that an LTCH patient have a prior hospital stay that includes three days or more in the intensive care unit (ICU) in order to qualify for the full payment rate would ensure they are able to add capacity to the health care system by caring for appropriate patients, without penalty.

Alternative Payment Model (APM) Flexibility. Deeming coronavirus an ‘extreme and uncontrollable circumstance’ for APMs that have significant hardship policies would allow the agency flexibility in making adjustments to the APM specifications, such as for episode spending or quality measurement. This would help ensure that providers are not penalized for circumstances beyond their control.

Supplemental Payments. Allow states to create new time-limited supplemental hospital payment mechanisms (fee for service and managed care) to address COVID-19 related treatment, services, testing without CMS prior approval if state appropriately documents program.

Temporary Waiver of Certain Payment Caps. Allow states to suspend any Upper Payment Limit restrictions or Medicaid DSH hospital-specific caps to address hospital payments for COVID-19 related treatment, services, testing without CMS prior approval if state appropriately documents such payments.

Site-neutral Payment Cuts. Immediately cease paying claims for clinic visits provided at excepted off-campus provider-based departments at the reduced payment rate implemented with the 2020 Medicare final rule governing the hospital outpatient prospective payment system. Instead such clinic visit claims should be paid at the rate that would have been in effect absent the payment reduction. Refraining from reducing resources in this manner would help ensure patients get the care they need.