August 18, 2020

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

Subject: Hospitals Without Walls Stakeholder Engagement Feedback

Dear Administrator Verma:

The Federation of American Hospitals (FAH) appreciates the opportunity to have participated in CMS’s Stakeholder Session on the Hospital Without Walls (HWW) waivers hosted on August 13. In follow up to the discussion and our letter of July 10 (attached) outlining our position on various waivers implemented by CMS over the course of the Public Health Emergency (PHE), we wish to offer some additional feedback that we hope will be reflected in your ongoing evaluation of the waivers and guide future policy making in this area.

The HWWs are and will remain a critical and necessary policy lever to ensure that hospitals have the necessary tools to pivot quickly to meet the needs of their communities in responding to COVID-19 or other PHE. This includes increasing bed capacity to address the acutely- and critically-ill when a community experiences or anticipates a surge of cases due to COVID-19 or other PHE, establishing alternative care sites for testing and providing other services, and partnering with post-acute care providers to increase bed capacity and ensuring that patients continue to be safely discharged following their hospital stay. FAH members have utilized many of the HWW waivers and are grateful for the flexibility to choose the waiver(s) that best meet their unique needs.
We appreciate CMS providing a variety of HWW regulatory flexibilities that a hospital can exercise to respond to the pandemic. However, given the ever-evolving nature and spread of COVID-19, it is difficult to precisely catalogue and quantify their application across the health care delivery system. Hospital and health system plans are necessarily dynamic to enable rapid responses to changing circumstances, and decisions on which waiver works best in a particular situation vary accordingly and are not made in isolation.

FAH members report that decisions to increase bed capacity are informed by both the data on current case counts and hospitalizations (including the predictive modeling that leverages that data) and ongoing dialogue with community partners at the local and state level. As hospitals and health systems make decisions about increasing bed counts, creating alternative care sites, or utilizing unused space, several factors are weighed to ensure that financial and human resources are available and used efficiently, including clarity about payment mechanisms for services provided in alternate care sites as well as uncertainty about whether specific waivers will continue under the PHE or whether declaration of the PHE will be extended appropriately. In addition, state agencies play a critical role. For example, a decision by a state to waive health and safety codes may make it easier for a hospital to quickly convert existing unused space, whereas in other states, setting up an alternative care site completely off campus may be the less costly or regulatory burdensome approach. Further, in some states, hospitals and health systems are given very specific direction from local and state officials regarding how and when they can increase bed capacity. FAH members have shared the following:

- The ability to provide services remotely via telehealth to patients in their homes has been essential and allowed hospitals to continue to provide patient-centered health care services conveniently to every facet of their community. This is particularly true for oncology and behavioral health services. As evidenced by the questions that continue to come up in the CMS office hour calls, the biggest challenge providers face is in understanding how to bill correctly under the OPPS for services provided to patients in their homes.

- HWW waivers have been utilized to provide care on campus in previously unused spaces, offsite, and in various locations as directed by state and local governments.

- For hospitals and health systems with existing swing beds, the swing bed waiver has been utilized successfully along with the waiver of the three-day qualifying stay for skilled care. These waivers have been particularly important in states like Florida where discharges to skilled nursing facilities (SNFs) have posed a significant challenge. For hospitals and health systems with little to no prior experience in billing for swing beds, this waiver has significant barriers to implementation. FAH members report that the cost of compliance with minimum data set (MDS) reporting for billing purposes has been the most significant barrier to implementation. We urge CMS to consider additional flexibility including waiving the MDS requirements to ensure that this waiver can be more broadly utilized. In addition, we urge CMS to work with Congress to create an alternative payment methodology for acute care hospitals under the IPPS, rather than the SNF PPS to more accurately reflect the hospital cost of providing care to Medicare beneficiaries.
IRFs and LTCHs provide hospital level care that has been critical in working with their acute care partners in providing increased bed capacity and through-put, and more flexibility around discharge planning. The waivers of the IRF 60% rule and 3-hour rule, as well as the LTCH 25-day average length of stay continue to be essential in allowing IRFs and LTCHs to use their specialized expertise to assist in caring for patients during the PHE. FAH members report that these waivers have been utilized in many areas around the country, in NY, NJ, MI, TX, AZ, FL, and AL. More specifically, IRFs have played a critical role in getting all patients, including COVID-19 patients, back to important activities of daily living. In addition, LTCHs have utilized customized care pathways for their critically ill patients including ventilator weaning for recovering COVID-19 patients. IRFs and LTCHs are providing patients safe, high-quality care that has not resulted in widespread COVID-19 outbreaks or increased mortality. These specific waivers are critical to the success of the HWW waivers and must remain in place for the duration of the PHE, with an appropriate “glide path” rather than a hard stop for phasing out the waivers, as is needed for all waivers in effect during the PHE.

Compliance with the Medicare hospital conditions of participation (CoPs) is critical to ensuring patient safety and high-quality care. However, the CoPs also contribute to the cost of providing care. CMS waivers of several COPs has streamlined the ability of hospitals and health systems to look across their workforce and think creatively about utilization of clinical resources while staffing alternative care sites. For example, CMS permitting Qualified Medical Personnel (QMP) on-campus or offsite – acting within their scope of practice as determined by the state and approved by the hospital’s governing body – to perform medical screening examinations is just one example of the efficient use of the health care workforce. Additionally, removing the antiquated and redundant requirement for nursing staff to maintain a comprehensive care plan has decreased burden and allows for nursing staff to dedicate more time to direct patient care.

This PHE has highlighted the success of virtual care delivery, and the FAH appreciates the flexibilities provided by CMS and Congress with regard to telemedicine and other forms of virtual care. However, the cost of the technology in addition to the resources needed to support the clinician should not be overlooked. Further, as CMS evaluates the cost of the HWW waivers, we encourage CMS to acknowledge the varied cost structure of each provider in providing these services. For example, hospital outpatient departments still have a much higher regulatory burden than other providers. As such, Medicare payment for certain hospital outpatient department (HOPD) services furnished to patients in a remote location, such as their home or other setting, should continue to be paid under the OPPS as if the service had been provided in the HOPD.

Finally, as noted in our July 10 letter, there are a number of waivers that we believe should be discontinued at the end of the PHE. For example, the Physician Self-Referral Law (Stark Law) should not be waived to allow physician-owned hospitals to increase licensed beds and operating/procedure rooms nor should physician-owned ambulatory surgery centers (ASCs) be permitted to enroll as physician-owned hospitals with a Stark Law physician ownership waiver. Self-referrals to physician-owned hospitals are mired in conflicts of interest, and years of independent data show that such arrangements result in cherry-picking of the healthiest and
wealthiest patients, excessive utilization of care, and patient safety concerns at significant cost to patients and the Medicare program.

In addition, independent non-provider-based free-standing emergency departments (IFEDs) should not be permitted to enroll in Medicare and receive Medicare payment. These facilities are not affiliated with a hospital and thus do not have the breadth of clinical and other resources needed for ongoing continuity of patient care and are not subject to CMS guidelines and regulations related to emergency department operations.

We appreciate the opportunity to provide these thoughts for your consideration and look forward to providing additional information as it becomes available. If you have any questions, please do not hesitate to contact me at 202-624-1534.

Sincerely,

cc: Alina M. Czekai, MPH
July 10, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Dear Administrator Verma:

The Federation of American Hospitals (FAH) is the national representative for over 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural America. Our members include teaching and non-teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children’s, and cancer services.

We commend your leadership and support of hospitals as they continue to address patient needs throughout this COVID-19 public health emergency (PHE). In particular, the numerous regulatory waivers and implementation of legislatively mandated waiver policies have been critical in allowing hospitals to prepare for patient surge and continue to care for patients throughout the PHE, while also protecting them from risk of exposure to COVID-19.

Hospitals rely heavily on these administrative flexibilities to meet patient demand and care for COVID-19 and non-COVID-19 patients, and many of the waivers have been transformational for our health care system in terms of utilizing technology to modernize and redesign how care is delivered. In fact, these new flexibilities and innovations have allowed hospitals to continue to provide patient-centered health care services conveniently to every facet of their community.
Therefore, hospitals are concerned about the expiration or elimination of a number of these waivers when it becomes safe to transition from the PHE to rebuilding hospital standard operations in a post-COVID-19 environment. For example, existing waivers that permit the treatment of hospital outpatients at home through remote monitoring technology as well as many telehealth waivers have enabled hospitals and health systems to continue to care for patients who lack access to transportation or for whom visiting the hospital could put them at risk.

To that end, we support CMS’ concept of a "glide path" for phasing out temporary policies put into effect during the PHE, rather than a hard stop. Significant advance notice of the end of the PHE to allow planning time for hospitals so that they can maintain continuity of care for patients when our system transitions from COVID-19 trauma care back to normal operations. We also urge a similar glide path for any COVID-19 blanket waivers that may be lifted during the PHE, as this allow hospitals to request an individual waiver for specific instances where the waiver may be still be warranted.

In addition, we support CMS’ efforts to transform certain temporary waivers into permanent Medicare policy and look forward to working with the new CMS Office of Burden Reduction and Health Informatics to assist in achieving these meaningful and lasting policy changes across our health care system. In some cases, Congressional action may be needed to ensure a smooth transition, and we urge CMS to work expeditiously with Congress to act on policies that require such action to become permanent Medicare policy.

Importantly, other waivers should be allowed to expire at the end of the PHE (with an adequate glide path in place), but with the ability to incorporate them into a “blanket” waiver that can be activated during any future pandemic or similar PHE.

Attached is a list of the waivers that we urge CMS to act upon for permanent Medicare policy status as well as those that should expire, while noting the expiring waivers that should automatically be activated under a blanket waiver in a future PHE.

Hospitals and health systems have adapted quickly to meet the needs of patients and their communities during this pandemic, including the rapid adoption and deployment of technology to provide much needed health care services in patients homes. This PHE has highlighted the success of virtual care delivery, and the FAH appreciates the flexibilities provided by CMS and Congress with regard to telemedicine and other forms of virtual care. An overarching principle that we urge both CMS and Congress to take into account when developing new, permanent Medicare policy based on these waivers and flexibilities is that payment for health care services provided remotely through technology should reflect differences in the cost-structure of the entity providing the service. For example, Medicare payment for certain hospital outpatient department (HOPD) services furnished to patients in a remote location, such as their home or other setting, should be paid under the outpatient prospective payment system (OPPS) as if the service had been provided in the HOPD. This will help ensure that all patients have access to critical Medicare services that can be performed remotely while ensuring that elderly and other patients receive care safely in their home.
Again, we so appreciate your service as well as the dedication, diligence, and leadership that you and your staff at CMS have provided at each step of the way throughout this pandemic. We look forward to continuing our work with you to ensure that hospitals can continue to provide quality care to their patients during this PHE and apply “lessons learned” during this time to transform and modernize Medicare policies. Please feel free to contact me or any member of my staff to discuss further these important matters at (202) 624-1534.

Sincerely,

[Signature]
WAIVERS THAT SHOULD TRANSITION TO PERMANENT MEDICARE POLICY

Remote Services Provided Through the Use of Technology

- **At Home HOPD Services**: Allow Medicare payment for certain HOPD services provided in the patient home or other setting (e.g., partial hospitalization program services (PHP); independent/group therapy; congestive heart failure clinic services), with payment under the outpatient prospective payment system as if the service had been furnished in the HOPD.

- **Geographic and Originating Site**: Eliminate the Medicare telehealth geographic and originating site restrictions to allow these services to be provided via urban hospitals, physician offices, and patient homes in any area of the country.

- **Eligible Practitioners**: Expand the list of eligible practitioners who may furnish clinically appropriate health care services via remote technology, including licensed professional counselors (LPCs).

- **Expanded Medicare Physician Fee Schedule (MPFS) Coverage/Payment**: Continue expanded coverage/payment under the MPFS, including:
  - **Physician or advanced practice practitioner** (APP) services (e.g., physician/APP consults for patients in the emergency department, critical care services, therapy services, and initial and continuing intensive care services).
  - **Remote patient monitoring** (RPM) for new or established patients with any single chronic or acute conditions, including monitoring a patient in their home post-surgery to help avoid hospital readmissions.
  - **Virtual check-ins and e-visits** when furnished to new patients.
  - **Audio-only E/M services** for audio-only E/M (CPT 99441-99443), with an appropriate payment differential.
  - **Direct supervision** requirement is satisfied by the virtual presence of a physician (for purposes of “incident to” and “teaching physician” services) through audio/video real-time communications technology.
  - **Resident services under the primary care exception** allowed for an expanded list of services, including audio-only evaluation and management, e-visits, inter-professional consultations, transitional care management, virtual check-ins, and remote evaluations.

- **Telehealth Consent Process**: Eliminate the separate consent process for telehealth services and use the telehealth encounter as presumed consent.

- **Qualified Medical Personnel (QMP)**: Permit QMPs to perform medical screening examinations (MSEs) via telehealth; permit the QMP to be on-campus or offsite (due to...
staffing shortages) but must be performing within the scope of their state scope of practice act and approved by the hospital’s governing body to perform MSEs.

- **Rural Health Clinics/Federally Qualified Health Centers**: Allow Medicare payment for telehealth services furnished in rural health clinics and federally qualified health centers, and work with stakeholders to support fair and appropriate payment for these safety net providers.

- **Waiver of Frequency Limits**: Allow subsequent hospital care services and critical care services to be furnished via telemedicine without limiting these telehealth services to once every three days, or once per day, respectively.

- **In-State Licensure Flexibility**: Allow licensed out-of-state physicians/non-physician practitioners (NPPs) to provide telehealth to patients across state lines without having to obtain licensure in the state where the patient is located (while recognizing that state waivers or licensure compacts also would be needed.)

- **Relaxation of Credentialing by Proxy Written Agreement Requirement**: Allow a spoke hospital to rely on the credentialing decisions (for a telehealth physician) of a distant site hub hospital, with no written agreement, to memorialize that the hub hospital fulfilled all the hospital conditions of participation (CoP) requirements for credentialing and privileging.

**Clinical Services**

- **Nursing Staff**: Remove requirement for nursing staff to maintain a comprehensive care plan as this is an antiquated and redundant requirement that detracts from the nursing staff’s care of the patient; alternatively, the nursing care plan could focus on several key patient problems at issue during the patient’s hospital stay, while the clinical medical record would instead represent the entire care plan and related medical interventions.

**Lab Services**

- **Pathology Review**: Allow pathologists to review pathology slides remotely without the need for a separate CLIA certificate for the remote location.

- **COVID-19/Influenza Lab Testing**: Allow Medicare payment for COVID-19 (and influenza) and other related diagnostic lab testing without an order from a treating physician or APP.

**Post-Acute Care/Discharge Planning**

- **Patient Choice Requirement**: Regulatory discharge requirement that providers must furnish a list of home health agencies (HHAs), skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs) and long-term-care hospitals (LTCHs) that are available to the
patient should be permanently streamlined. We urge CMS to work with affected stakeholders to establish appropriate regulatory guardrails that achieve a balance of protecting patient choice and ensuring access to appropriate levels of high-quality care with the need for specific information that is most beneficial for patients when being discharged to post-acute care facilities.

**Behavioral Health**

- Allow advance practice nurses to serve in the attending role for Medicare patients, *e.g.*, diagnose, treat, admit patients with mental illness, and not require physician supervision.

- Remove discharge planning requirements for post-acute care from psychiatric facilities since patients typically are not transferred from psychiatric facilities to post-acute care providers.

**WAIVERS THAT SHOULD EXPIRE AFTER THE PHE**

**Post-Acute Care/Discharge Planning**

- **60 Percent Rule**: Waiver of IRF 60 percent rule, which eliminates restrictions on access to rehab services (*i.e.*, 60 percent of patients must be discharged from hospital with one of 13 qualifying conditions) even if the patients otherwise meet IRF admission criteria has been an important waiver and should continue in effect throughout the PHE, after which the rule should be reexamined in the context of developing a regulatory framework that most appropriately promotes patient-centered care.

- **3-Hour Rule**: Requirement that IRF patients must receive at least 15 hours of therapy per week/three hours per day (3-Hour Rule) should expire.

- **3-Day Prior Hospitalization**: Requirement for a 3-day prior hospitalization for coverage of a SNF stay should expire.

- **Swing Bed Expansion**: Requirements for removing the rural / less than 100 bed limitation for hospitals to operate and receive reimbursement for SNF swing beds should expire.

- **LTCH 25-Day Rule**: Requirement allowing LTCHs to exclude emergency admits/discharges from the 25-day average length of stay requirement should expire.

**Telehealth**

- **HIPAA Privacy and Technology Security Standards**: OCR enforcement waiver to permit use of non-HIPAA compliant technology for telehealth should expire (*e.g.*, no FaceTime and Skype).

*These requirements should be part of a blanket waiver for any future PHE; bullets above that we recommend expire at the end of the PHE that do not contain an asterisk may or may not be needed on a temporary basis in a future PHE, and any such determination should be made in consultation with appropriate stakeholders.*
**Graduate Medical Education (GME)**

- **Resident Moonlighting***: Resident moonlighting in their own host GME program should expire.

**Sites of Care**

- **Physician-Owned Hospitals**: Do not waive the part of the Physician Self-Referral Law (Stark Law) to allow physician-owned hospitals to increase licensed beds and operating/procedure rooms.

- **Physician-Owned ASCs**: Do not allow physician-owned ambulatory surgery centers (ASCs) to enroll as physician-owned hospitals with a Stark Law physician ownership waiver.

- **Physician Group Practices***: Do not waive portions of the Stark Law to permit physicians in “group practices” to order medically necessary “designated health services” (e.g., lab, imaging, other ancillaries, etc.) in a patient’s home or other non-group practice location.

- **Non-Provider-Based FSEDs**: Do not allow independent non-provider-based free-standing emergency departments (FSEDs) to enroll in Medicare and receive Medicare payment.

- **Ambulance Transport**: Revert to allowable destinations for ambulance transports to the pre-COVID19 list; do not allow ambulances to transport patients to a wider variety of settings (e.g., physician’s offices, urgent care facilities, ASCs).

- **Billing for Services Outside a Facility**: Do not allow hospitals to bill for services provided outside of their facility as part of a temporary expansion site under the hospitals without walls initiative (note that this should not affect treating patients in their home using remote technology.)

*These requirements should be part of a blanket waiver for any future PHE; bullets above that we recommend expire at the end of the PHE that do not contain an asterisk may or may not be needed on a temporary basis in a future PHE, and any such determination should be made in consultation with appropriate stakeholders.