DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

March 26, 2020

Maureen Keehnle
Senior Vice President and General Counsel
Iowa Hospital Association
100 Grand Ave #100
Des Moines, IA 50309
[email: keehnlem@ihaonline.org]

Re: Section 1135 Flexibilities Requested in March 24, 2020 Communication

Dear Ms. Keehnle:

On March 13, 2020, President Trump issued a proclamation declaring that the COVID-19 outbreak in the United States constitutes a national emergency under sections 201 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.). On March 13, 2020, pursuant to section 1135(b) of the Social Security Act (Act), the Secretary of the Department of Health and Human Services invoked his authority to waive or modify certain requirements of titles XVIII, XIX, and XXI in response to the COVID-19 pandemic. The Secretary is exercising such authority as necessary to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the aforementioned Medicare and Medicaid programs. Such waivers also ensure that health care providers who furnish items and services in good faith, but maybe unable to comply with one or more program requirements as a result of the COVID-19 pandemic, may be reimbursed and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse. This authority took effect as of 6 p.m. Eastern Daylight Time on March 17, 2020, with a retroactive effective date of March 1, 2020. Once the national emergency terminates, including any extensions, section 1135 waivers will no longer be available.

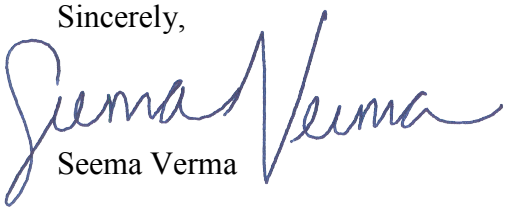
On March 24, 2020, you detailed to the Centers for Medicare & Medicaid Services (CMS) a number of federal Medicaid and Medicare requirements that pose challenges for the health care delivery system in Iowa, and requested a waiver or modification of those requirements. Attached, please find a response, granting some of the waivers and modifications you requested, pursuant to section 1135 of the Act, to address the challenges posed by the COVID-19 pandemic.

To streamline the section 1135 waiver request and approval process, CMS has issued and may continue to issue blanket waivers for many Medicare provisions, which primarily affect requirements for individual facilities, such as hospitals, long-term care facilities, home health agencies, and others. Waiver or modification of these blanket provisions does not require individualized approval. For information on provisions waived or modified under our blanket

waiver authority, please refer to guidance available at https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf

Please contact Linda Smith, Division Director in the Survey & Operations Group at (404) 562-7469 or by email at linda.smith@cms.hhs.gov if you have any questions or need additional information. We appreciate the efforts of you and your staff in responding to the needs of beneficiaries in your State and health care community.

Sincerely,



Seema Verma

Attachment(s)

THIS SERVES AS OFFICIAL NOTICE SENT VIA EMAIL OR FACSIMILE PURSUANT TO 42 CFR §488. NO HARD COPY TO FOLLOW.

Enclosure – Additional Approved Waivers

Hospitals, Psychiatric Hospitals, and CAHs:

- **Emergency Medical Treatment and Active Labor Act (EMTALA).** CMS is waiving the enforcement of section 1867(a) of the Social Security Act (the Emergency Medical Treatment and Active Labor Act, or EMTALA). This will allow hospitals, psychiatric hospitals, and CAHs to screen patients at a location offsite from the hospital's campus to prevent the spread of COVID-19, in accordance with the state emergency preparedness or pandemic plan.

- **Verbal Orders.** CMS is waiving the requirements of §482.23, §482.24 and §485.635(d)(3) to allow for additional flexibilities related to verbal orders where read-back verification is still required but authentication may occur later than 48 hours. This will allow for more efficient treatment of patients in a surge situation. Specifically, the following requirements are waived:
  - §482.23(c)(3)(i)- If verbal orders are used for the use of drugs and biologicals (except immunizations), they are to be used infrequently;
  - §482.24(c)(2) - All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient;
  - §482.24(c)(3)- Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders. This would include all subparts at §482.24(c)(3).
  - §485.635(d)(3)- Although the regulation requires medication administration be based on a written, signed order, this does not preclude the CAH from using verbal orders. A practitioner responsible for the care of the patient must authenticate the order in writing as soon as possible after the fact.

- **Reporting Requirements**. CMS is waiving the requirements at 42 C.F.R. §482.13(g)(1)(i)-(ii) which require hospitals to report patients in an intensive care unit whose death is caused by their disease process but who required soft wrist restraints to prevent pulling tubes/IVs may be reported later than close of business next business day, provided any death where the restraint may have contributed is continued to be reported within standard time limits. Due to current hospital surge, we are waiving this requirement to ensure hospitals are focusing on increased care demands and patient care.

- **Patient Rights.** 42 C.F.R. §482.13. CMS is waiving requirements under this section only for hospitals which are considered to be impacted by a widespread outbreak of COVID-19. Hospitals that are located in a State which has widespread confirmed cases (i.e., 6-50 or more confirmed cases), as updated under the CDC States Reporting Cases of COVID-19 to CDC at https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html would not be required to meet the following requirements:
  - 42 C.F.R. §482.13(d)(2) with respect to timeframes in providing a copy of a medical record.

  - 42 C.F.R. §482.13(h) related to Patient visitation, including the requirement to have written policies and procedures on visitation of patients who are in COVID-19 isolation and quarantine processes.
  - 42 C.F.R. §482.13(e)(C)(1)(ii) regarding seclusion.

- **Sterile Compounding.** 42 C.F.R. §482.25(b)(1) and §485.635(a)(3). CMS is waiving these requirements in order to allow used face masks to be removed and retained in the compounding area to be re-donned and reused during the same work shift in the compounding area only. This will conserve scarce face mask supplies which will help with the impending shortage of medications. While USP797 also outlines this, CMS will not be reviewing the use and storage of facemasks under these requirements.

- **Detailed Information Sharing for Discharge Planning for Hospitals and CAHs:** CMS is waiving the requirement to provide detailed information regarding discharge planning as outlined in 42 C.F.R. §482.43(a)(8), §482.61(e), and 485.642(a)(8), described below:

  The hospital, psychiatric hospital, and CAH must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The hospital must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

- **Discharge Planning for Hospitals.** 42 C.F.R. §482.43(c) CMS is waiving all the requirements and subparts related to post-acute care services, so as to expedite the safe discharge and movement of patients among care settings, and to be responsive to fluid situations in various areas of the country. CMS is waiving the requirement that for those patients discharged home and referred for HHA services, or for those patients transferred to a SNF for post-hospital extended care services, or transferred to an IRF or LTCH for specialized hospital services, the hospital must:
  - §482.43(c)(1) include in the discharge plan a list of HHAs, SNFs, IRFs, or LTCHs that are available to the patient.
  - §482.43(c)(2) must inform the patient or the patient's representative of their freedom to choose among participating Medicare providers and suppliers of post-discharge services ....and that,
  - §482.43(c)(3) The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare.

- **Medical Staff.** 42 C.F.R. §482.22(a) and §485.627(a).CMS is waiving these requirements to allow for physicians whose privileges will expire to continue practicing at the hospital or CAH and for new physicians to be able to practice in the hospital or CAH before full medical staff/governing body review and approval.

- **Medical Records Timing.** 42 C.F.R. §482.24(c)(4)(viii) and §485.638(a)(4)(iii). CMS is waiving these requirements related to medical records to allow flexibility in completion of medical records within 30 days following discharge and for CAHs that all medical records must be promptly completed. This flexibility will allow clinicians to focus on the patient care at the bedside during the pandemic.

- **Flexibility in Patient Self Determination Act Requirements (Advance Directives):** CMS is waiving the requirements at section 1902(a)(58) and 1902(w)(1)(A) for Medicaid, 1852(i) (for Medicare Advantage); and 1866(f) and 42 CFR 489.102 for Medicare, which require hospitals and CAHs to provide information about its advance directive policies to patients. We are waiving this requirement to allow for staff to more efficiently deliver care to a larger number of patients. This would not apply to the requirements at §482.13(a) for hospitals and at §485.608(a) for CAHs to receive information about the presence of a policy regarding the facility's recognition of advanced directives.

- **Physical Environment:** CMS is waiving certain requirements under the Medicare conditions at 42 C.F.R. §482.41 and §485.623 to allow for flexibilities during hospital, psychiatric hospital, and CAH surges. CMS will permit non-hospital buildings/space to be used for patient care and quarantine sites, provided that the location is approved by the State (ensuring safety and comfort for patients and staff are sufficiently addressed). This allows for increased capacity and promotes appropriate cohorting of COVID-19 patients.

Skilled Nursing Facilities

- **Staffing Data Submission:** CMS is waiving 42 CFR 483.70(q) to provide relief to long term care facilities on the requirements for submitting staffing data through the Payroll-Based Journal system.

- **Waive Pre-Admission Screening and Annual Resident Review (PASARR):** CMS is waiving the following requirements related to PASARR for nursing home residents who may also have a mental illness or intellectual disability (42 CFR §483.106(b)(4)).
    - Level I screens are not required for residents when they are being transferred between NFs (inter-facility transfers) and staff cannot enter nursing facilities due to quarantine. If the NF is not certain whether a Level I evaluation had been conducted at the resident's transferring/evacuating facility, a Level I can be conducted by the admitting facility during the first few days of admission as part of intake. If there is not enough information to complete a Level I evaluation, the NF must document this in the resident's case files. Level II evaluations and determinations are also not required preadmission when residents are being transferred between NFs. Residents who are transferred will receive a post admission review which must be completed as resources become available.

- **Physical Environment.** Provided that the State has approved the location as one that sufficiently addresses safety and comfort for patients and staff, CMS is waiving requirements under §483.90 to allow for a non-SNF buildings to be temporarily certified

as and available for use by a SNF in the event there are needs for isolation processes for COVID-19 positive residents which may not be feasible in the existing SNF structure to ensure care and services during treatment for COVID-19 is available while protecting other vulnerable adults. CMS believes this will also provide another measure that will free up inpatient care beds at hospitals for the most acute patients while providing beds for those still in need of care. CMS will revise processes, as necessary, to facilitate certification and surveys of these sites under this waiver. Waiver of certain conditions of participation and certification requirements for opening a NF if the state determines there is a need to quickly stand up a temporary COVID-19 isolation and treatment location**.**

- **Resident Groups.** CMS is waiving the requirements at §483.10(f)(5) which allow for residents to have the right to participate in-person in resident groups. This waiver would only permit the facility to restrict having in-person meetings during the national emergency given the recommendations of social distancing and limiting gatherings of more than ten people. Refraining from in-person gatherings will help prevent the spread of COVID-19.

- **Training and Certification of Nurse Aids** CMS is waiving the requirements at §483.35(d) which requires that a SNF and NF may not employ anyone for longer than 4 months unless they met the training and certification requirements under §483.35(d). CMS is waiving these requirements to assist in potential staffing shortages seen with the COVID-19 pandemic.

Home Health Agencies

- **Reporting**: Provides relief to Home Health Agencies on the timeframes related to OASIS Transmission. **(Approved on 3/13/2020- Clarified)** This waiver includes:
    - Extension of the 5-day completion requirement for the comprehensive assessment
    - Waives the 30-day OASIS submission requirement

- **Home Health 42 C.F.R. § 484.55(a).** Home health agencies can perform initial assessments and determine patients' homebound status remotely or by record review. This will allow patients to be cared for in the best environment while supporting infection control and reducing impact on acute care and long-term care facilities. This will allow for maximizing coverage by already scarce physician and advanced practice clinicians and allow those clinicians to focus on caring for patients with the greatest acuity.

Hospice:

- **Waive requirement for hospices to use volunteers**. CMS is waiving the requirement that hospices are required to use volunteers (including at least 5% of patient care hours). It is anticipated that hospice volunteer availability and use will be reduced related to COVID-19 surge and anticipated quarantine. (42 CFR §418.78(e))

- **Comprehensive Assessments**: CMS is waiving certain requirements for Hospice (§418.54) related to update of the comprehensive assessments of patients. This waiver applies the timeframes for updates to the comprehensive assessment (§418.54(d)). Hospices must continue to complete the required assessments and updates, however, the timeframes for updating the assessment may be extended from 15 to 21 days.

- **Waive Non-Core Services**: CMS is waiving the requirement for hospices to provide certain non-core hospice services during the national emergency, including the requirements at §418.72 for physical therapy, occupational therapy, and speech-language pathology.

Home Health & Hospice:

- **Waived onsite visits for both HHA and Hospice & Aide Supervision**: CMS is waiving the requirements at 42 CFR 418.76 (h) and 484.80(h), which require a nurse to conduct an onsite visit every two weeks. This would include waiving the requirements for a nurse or other professional to conduct an onsite visit every two weeks to evaluate if aides are providing care consistent with the care plan as this may not be physically possible for a period of time. This waiver is also temporarily suspending 2-week aide supervision requirement at 42 CFR §484.80(h)(1) by a registered nurse for home health agencies, but virtual supervision is encouraged during the period of the waiver.