April 8, 2020

VIA EMAIL AND U.S. MAIL:
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Douglas O'Brien
Regional Director
CMS Chicago Regional Office
Centers for Medicare & Medicaid Services
Chicago Regional Office
233 N. Michigan Ave., Suite 1300
Chicago, IL 60601

Re: Section 1135 Waiver Request Related to Novel Coronavirus Disease (COVID-19)- Requirements of Participation

Dear Director O'Brien,

On March 13, 2020, The President of the United States declared an emergency under the National Emergencies Act or Stafford Act and the HHS Secretary declared a Public Health Emergency Declaration under Section 319 of the Public Health Service Act. In response, the HHS Secretary exercised his authority to take certain actions in addition to regular authorities, to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid and CHIP programs and to ensure that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of these requirements as a result of the consequences of the COVID-19 pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse.

Included in the Secretary's foundational 1135 waiver issued on March 13, 2020 was flexibility to waive certain conditions of participation, certification requirements, program participation or similar requirements for individual health care providers or types of health care providers, including as applicable, a hospital or other provider of services, a physician or other health care practitioner or professional, a health care facility, or a supplier of health care items or services, and pre-approval requirements.

In this time of national public health emergency, the State of Indiana is facing a growing staffing crisis, shortages of vital resources including personal protective equipment (PPE), as Indiana is not expected to receive further inventory from the national strategic stockpile at this time, and constraints on their capacity to meet every regulatory Requirement of Participation. As efforts to prevent and mitigate the spread of the virus intensify and resident care needs grow due to aggressive infection control practices, increased screening, and cancelling of communal dining and activities, coupled with lower staffing levels due to staying home when symptomatic and child care issues related to closed schools, long term care

facilities need relief from certain requirements and flexibility to ensure they are able to use every available resource to meet residents' needs in this critical time.

Further, Indiana has begun to experience COVID-19 outbreaks in long-term care facilities, expediting the need for flexibility in order to respond quickly to evolving circumstances. The state and long-term care industry's efforts to create COVID-dedicated buildings to cohort COVID-positive patients, and allow for hospitals to transfer patients no longer needing acute care to regional facilities, also underscores the need for additional waivers to address the unique requirements of these dedicated facilities. We appreciate CMS's and the State's actions to date to provide regulatory flexibilities, including state waivers and new blanket waivers issued by CMS on March 30, 2020, to help long term care providers manage the spread of COVID-19. Consistent with and in order to support HHS, CMS, and State goals to expand provider capacity and access to services and increase flexibility in the delivery of service, we would like to request the following additional flexibilities under an 1135 Waiver for the State of Indiana**.**

Dispensation is requested until: We request these waivers and modifications to become effective as of April 9, 2020 and be retroactive to March 1, 2020, and continue through the period described in Section 1135(e) and a reasonable post-emergency period, to the extent authorized by HHS.

Waiver Requests:

1. Temporarily waive certain requirements for admission, transfer, and discharge (§483.15) to provide relief and flexibility to long term care facilities, in addition to existing waivers, including:
    a. Allow center(s) to exceed their bed license capacity, to the extent permitted by state law. This flexibility would free up inpatient care beds at hospitals for the most acute patients while providing available beds for those still in need of care.
    b. Waive transfer and discharge requirements, including:
        i. Allow facilities to discharge residents who themselves or their family members refuse to abide by facility requirements to prevent the spread of COVID-19 (e.g., elect to leave the facility or mingle in the community or at gatherings outside the facility against policies and guidance, thereby increasing the possibility of their acquiring the virus and bringing it back into the facility).
        ii. §483.15(e)(2) Readmission to a composite distinct part.

2. Temporarily waive certain requirements in order to maximize capacity and staff availability for patient care and mitigating the COVID-19 emergency, as well as requirements that are superseded by CMS and CDC guidance designed to manage and mitigate the emergency, such as visitation, activities, dining, and seclusion or room changes for purposes of infection prevention and control protocols. Waivers requested for all providers include:
    a. §483.10(f)(3), Right to participate in community activities inside and outside the facility, due to restrictions necessary for controlling spread of COVID-19 and §483.10(f)(7), Right to have family members or other resident representatives meet in the facility, due to necessary visitor restrictions.
    b. Care Planning flexibility is needed during the emergency to allow staff in all facilities to focus on patient care at the bedside during the pandemic. Waive specific timeframes required for certain care plan updates and meetings:

i. §483.21(b)(1) Compliance with timeframes exactly as indicated in care plan or plan of care such as medications, dialysis, meals
ii. §483.21(b)(2)(ii) Requirements for routine care plan meetings/conferences and required care plan attendance for all members of IDT and resident representative
iii. §483.21(b)(2)(iii) Timing of care plan reviews by entire IDT after each assessment
iv. §483.21(c)(1)(viii)-(ix) Discharge Planning Process. Temporarily waive requirements for providing specific detailed information in selecting a post-acute care provider for residents transferred to another SNF or a HHA, IRF, or LTCH in order to expedite safe discharge and movement of patients among care settings.

b. Activities: §483.24(c) In-person group activities are suspended according to CDC guidance to help prevent the spread of COVID-19.
c. Nursing Services:
    i. § 483.35(g)(4). Retention of daily posted nurse staffing data for 18 months.
d. Pharmacy services:
    i. §483.45(c) Temporarily waive monthly medication regimen reviews (drug regimen review) of medical chart and enable routine reviews to be conducted remotely/via telehealth options.
e. Waive routine/non-essential procedures including labs, dental, optometry and podiatry, to support facilities in implementing CDC's visitation guidance:
    i. §483.50(a) Routine labs
    ii. §483.55(a) & (b) Dental services
f. Food and nutrition services:
    i. §483.60(a)(2)(i) Certified dietary manager: Temporarily waive certification requirements for dietary manager.
g. Specialized rehabilitative services:
    i. §483.65(a) Wave face-to-face requirement and permit telehealth physical therapy, speech-language pathology, occupational therapy services – using 1135 waiver approved technology to interact with an isolated patient, their nurse, or nurse's aide in the presence of a patient from a separate location to reduce exposure to COVID-19.
        1. Permit SNF to report telehealth physical therapy, speech-language pathology, occupational therapy services in MDS items O0400 and O0425 as "Individual Minutes".
    ii. Waive any face-to-face regulatory, sub-regulatory, or contractor imposed "onsite supervisory limits" or similar requirements that a physical therapist or occupation therapist provide a face-to-face visit when a patient is being treated by a physical therapist assistant or occupational therapy assistant before the therapy/therapist assistant can continue care.
h. Telehealth services:

i. §410.78(b)(2) Waive the "practitioner" limits and add physical therapist, occupational therapist, and speech-language pathologist to the list of telehealth distant site "practitioners".
ii. §414.65(a) Waive the one telehealth visit per 30 days SNF telehealth frequency limits sub-regulatory policy located in the Medicare Claims Processing Manual, Chapter 12, Section 190.

i. Temporarily waive paperwork-related requirements such the Facility Assessment (§483.70(e)) and QAPI plan (§483.75(a)).
j. Temporarily waive required QAA meetings and QAPI program activity except for those addressing infection prevention and control and COVID-19 mitigation efforts (waive §483.75(g)(2) and all subparts implemented in Phase 3).
k. Waive mandatory staff training requirements (§483.95).

3. Fire and Life Safety: The current environment to limit the transmission of COVID-19 may restrict providers' ability to comply with the life safety and health care facility code requirements in LSC, HCFC and referenced codes and standards. Providers need waivers due to the widespread nature of this compliance issue and the need for consistent guidance. Facilities will, when possible, perform Alternative Life Safety Measures (ALSM). The focus of the ALSM would be measures that are readily achievable by facility personnel without the assistance of vendors. These include fire door checks, ensuring egress paths are clear, housekeeping, and surveillance of building grounds.
    a. Provide temporary relief from the following Life Safety Code® requirements involving specific quantities:
        i. Soiled linen and trash receptacles [LSC 19.7.5.7.1] – temporary increase for the capacity open to the corridor from a maximum of 32 gallons to 96 gallons due to the tremendous increase in biohazard items for disposal.
        ii. Alcohol-based hand-rubs (ABHRs) [LSC 19.3.2.6(5) and/or (7)] – allow higher aggregate quantities to be stored in a smoke compartment from a maximum of 10 gallons to 30 gallons. In addition, increase the capacity of individual containers from a maximum of 1.2 liters to 3 liters.
    b. Delay or extend the compliance for the requirements requiring inspection, testing and maintenance (ITM) by outside vendors as they may not be permitted in facilities during this crisis.
        i. Fire Alarm ITM [NFPA 72] – there would be a 60-day hiatus on fire alarm system ITM.
        ii. Water-Based Fire Suppression ITM [9.7.5, 9.7.7, 9.7.8, and NFPA 25] - there would be a 60-day hiatus on automatic sprinkler, standpipe and hose, fire hydrant, and fire pump ITM.
        iii. A 60-day hiatus for ITM of kitchen fire suppression systems, fire doors, fire and smoke dampers, portable fire extinguishers, emergency/standby generators, and elevators.
    b. In recognition of the additional burden and workload for facilities, and of delays in surveys and the performance of other administrative duties and responsibilities by authorities, permit the following extensions:

i. A 90-day extension on all expiring NFPA 101A Fire Safety Evaluation System (FSES) based waivers. FSES worksheets are typically handled by outside consultants such as licensed architects or professional engineers.
ii. A 120-day extension on all active Time Limited Waivers that will be expiring in the near term.

4. Staffing: Temporarily suspend certain staffing requirements to assist in mitigating staffing shortages caused by the COVID-19 pandemic:
    a. Feeding Assistant Training: We request a waiver of certain requirements for paid feeding assistants to enable facilities to expand capacity to meet residents' needs during the emergency. Allow nursing facility to use Temporary Feeding Assistants who have completed a training program of at least 1 hour approved by the state survey agency. These temporary feeding assistants are able to assist residents with meals and dining, with supervision from nursing staff and help from nursing staff in the event of an emergency. We request the following waivers:
        i. §483.60(h)(1)(i)-(ii)
        ii. §483.60(h)(2)(i)
        iii. §483.95(h)
    b. Hiring allowances:
        i. Allow staff from evacuated centers to work in receiving or other centers without usual pre-hire requirements, including but not limited to initial training and background check as these agencies are not accessible
        ii. Allow persons who have completed degree or certification program applicable to their position (including nursing, rehab therapist, social work, activities, and food/nutrition services) but not yet licensed, certified or registered, to meet this requirement:
            1. §483.70(f)(2) Professional staff must be licensed, certified, or registered in accordance with applicable State laws.
    c. Waive requirement for an RN to be present 8 hours a day, 7 days a week and for RN to serve as DON, [§483.35(b)].
    d. Due to closures of fingerprinting facilities and other related services, temporarily waive requirements for pre-hire screening, completion of criminal background checks which may include fingerprinting, and provisions required under the national background check program.

5. Survey:
    a. Enable remote/desk reviews for any needed follow-up survey activities except when on-site follow-up is absolutely necessary to verify IJ removal.
    b. Suspend required timeframes for:
        i. Plan of correction (POC) submission (for all non-IJ deficiencies). Regardless of timing of POC submission, compliance will be verified as of date of provider's allegation of compliance and penalties including per day CMPs and DDPNA will not accrue in the time period impacted by the suspended surveys and revisits.
        ii. Appeals including IDR and IIDR requests, to enable providers to submit appeal of deficiencies cited during the emergency after the emergency ends.
    c. Waive mandatory imposition of federal remedies including CMPs, 90-day DPNA, and 6-month (for non-IJ) termination of provider agreement

d. Relieve currently imposed penalties, specifically CMP, DPNA and nurse aide training suspension.

Sincerely,

Zach Cattell
President
Indiana Health Care Association/Indiana Center for Assisted Living

Eric Essley
President/CEO
LeadingAge Indiana

Terry Miller
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Hoosier Owners and Providers for the Elderly

cc: Indiana State Department of Health
Indiana Family and Social Services Administration