



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-20-24-ASC-**Revised**
Revised 11/25/2020

DATE: April 3, 2020
TO: State Survey Agency Directors
FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Guidance for Processing Attestation Statements from Ambulatory Surgical Centers (ASCs) Temporarily Enrolling as Hospitals during the COVID-19 Public Health Emergency *****REVISED*****

Memorandum Summary

- ***CMS is committed*** to taking critical steps to ensure America's health care facilities are prepared to respond to the COVID-19 Public Health Emergency (PHE).
- ***Waivers:*** CMS waivers adopted under the 1135 emergency waiver authority create additional flexibilities to allow enrolled ASCs to temporarily enroll as hospitals and to provide hospital services to help address the urgent need to increase hospital capacity to take care of patients.
- ***CMS Regional Office Processing of Attestations:*** This memorandum outlines the steps for processing attestations and certification kits for existing Medicare certified ASCs that choose to temporarily enroll as a hospital during the COVID-19 PHE.

Background

The Centers for Medicare & Medicaid Services (CMS) is providing needed flexibility to hospitals to ensure they have the ability to expand capacity and to treat patients during the COVID-19 PHE*. This includes waivers that permit implementation of these flexibilities. Due to the infrastructure that exists in most ASCs, these facilities have been identified as a critical resource to assist in expanding capacity for inpatient and outpatient hospital services for patients requiring a higher level of care. Consistent with the Hospitals without Walls strategy announced by the CMS Administrator, we expect ASCs to coordinate with their local healthcare systems and/or their state and local health departments operating under their state's emergency preparedness or pandemic plan during this PHE to help meet surge needs in their community.

Guidance

As part of the COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers (<https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf>).

During the COVID-19 PHE, CMS is allowing all Medicare-enrolled ASCs to enroll as hospitals and provide inpatient and outpatient hospital services to help address the urgent need to increase hospital capacity to take care of patients.

Any Medicare-certified ASC wishing to enroll as a hospital during the COVID-19 PHE should notify the Medicare Administrative Contractor (MAC) that serves their jurisdiction of its intent by calling the MAC's provider enrollment hotline and following the instructions noted in the [2019- Novel Coronavirus \(COVID-19\) Medicare Provider Enrollment Relief Frequently Asked Questions \(FAQs\) document](#). The ASC will be asked by the MAC to submit a signed attestation statement (see attachment to this memo) to the MAC. It should be noted that the provider cannot be certified/enrolled both as an ASC and hospital at the same time. If an ASC enrolls as a hospital, it must meet the hospital Conditions of Participation, to the extent not waived, and would receive hospital payments, not ASC payments. Therefore, any ASC that is enrolled as a hospital will have its ASC billing privileges deactivated for the duration of the time it is enrolled as a hospital.

The MAC will review and forward the signed attestation statement to the CMS RO mailbox, consistent with normal processes for ASC/hospital certification for further review. Within two business days, the CMS Regional Office (RO) will review all survey activity of the facility from the previous three years (recertification and/or complaint), to determine if Immediate Jeopardy (IJ)-level deficiencies were cited. For deemed status ASCs, CMS Central Office (CO) will provide a list to the CMS Survey Operations Group of those ASCs with IJ-level deficiencies cited within the previous three years.

If no IJ-level deficiencies were found in the previous three years, or if IJ-level deficiencies were found but subsequently removed through the normal survey process, the CMS RO will:

- Review and approve the attestation statement
- Create a new facility profile and certification kit in the Automated Survey Process Environment (ASPEN) and assign a hospital CMS Certification Number (CCN)
- Send a tie-in notice as a hospital to the MAC. The effective date of enrollment is the date when the attestation was accepted by the MAC.

Note that an onsite survey is not required for approval. However, the CMS RO may authorize a survey by the State Survey Agency at a later date to ensure quality and safety. If survey activity is warranted, it will be a focused infection control survey based on [QSO-20-20-ALL](#), and the availability of PPE as needed. Any need for enforcement actions would follow what is outlined in the referenced memo or any subsequent updates to the memo.

If IJ-level deficiencies are found within the last year and enforcement activities are currently ongoing, then the CMS RO will not accept the attestation and notify the MAC of denial of temporary hospital enrollment. No further actions will be taken to enroll the ASC as a hospital under this process.

Once the Secretary of the Department of Health and Human Services (Secretary) determines there is no longer a PHE due to COVID-19, the CMS RO will terminate the hospital CCN and send a tie-out notice to the applicable MAC. The MAC will deactivate the hospital billing privileges and reinstate the ASC billing privileges effective on the date the ASC terminates its hospital status. If the temporarily enrolled hospital decides to revert back to an ASC prior to the end of the PHE period, they must notify their MAC in writing. Note that once there is no longer a need for the

ASC to be a hospital under their state's emergency preparedness or pandemic plan, the ASC should come back into compliance with all applicable ASC federal participation requirements, including the Conditions for Coverage.

If the ASC wishes to participate as a hospital after the PHE has ended, it must submit form 855A to begin the process of enrollment and initial certification as a hospital under the regular processes. An initial survey, either done by the State Agency or Accreditation Organization, will be conducted to determine compliance with all applicable hospital Conditions of Participation. CMS will provide any additional updates if this process changes as the PHE progresses or ends.

As COVID-19 cases continue to surge, CMS remains committed to adapting program requirements to expand capacity and to treat patients during the PHE. For ASCs enrolling as hospitals during the PHE as part of the Hospitals Without Walls Program: CMS is waiving the particular requirement at 42 CFR §482.23(b)(1), which requires the hospital to have a licensed practical nurse or registered nurse on duty at all times. This waiver will only require ASCs enrolled as hospitals to provide 24-hour nursing services when there is a patient in the facility. This flexibility will allow ASCs enrolled as hospitals to provide nursing services on demand with a 24-7 on call service in the event a surgeon requests to admit a patient for a required surgical procedure. Waiver authority applies only to Federal requirements and does not supersede State requirements for licensure.

Additional Resources

*Public Health Emergency <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>

Section 3087 of the 21st Century Cures Act, signed into law in December 2016, added subsection (f) to section 319 of the Public Health Service Act. This new subsection gives the HHS Secretary the authority to waive Paperwork Reduction Act (PRA) (44 USC 3501 et seq.) requirements with respect to voluntary collection of information during a public health emergency (PHE), as declared by the Secretary, or when a disease or disorder is significantly likely to become a public health emergency (SLPHE). Under this new authority, the HHS Secretary may waive PRA requirements for the voluntary collection of information if the Secretary determines that: (1) a PHE exists according to section 319(a) of the PHS Act or determines that a disease or disorder, including a novel and emerging public health threat, is a SLPHE under section 319(f) of the PHS Act; and (2) the PHE/SLPHE, including the specific preparation for and response to it, necessitates a waiver of the PRA requirements. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) has been designated as the office that will coordinate the process for the Secretary to approve or reject each request.

The information collection requirements contained in this information collection request have been submitted and approved under a PRA Waiver granted by the Secretary of Health and Human Services. The waiver can be viewed at <https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers>.

Contact

Questions about this memorandum should be addressed to QSOG_ASC@cms.hhs.gov.

Effective Date

Effective immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators immediately. This guidance will cease to be in effect when the Secretary determines there is no longer a Public Health Emergency due to COVID-19. At that time, CMS will send public notice that this guidance has ceased to be effective via its website.

/s/
David R. Wright

cc: Survey and Operations Group Management
Attachment: (1)

Ambulatory Surgical Center (ASC) Hospital Enrollment Attestation Statement
For Use During COVID-19 Public Health Emergency (PHE)*

This attestation statement applies to: _____
(Legal Business Name of Entity)

D/B/A, if any: _____

Located at: _____
(Address, including street name and number, suite number if applicable, city, state, zip code)

Existing ASC CMS Certification Number (CCN): _____

In order to enroll as a Hospital during the COVID-19 PHE, the undersigned individual authorized by the ASC entity's Governing Body attests that the entity meets and will continue to meet, during the PHE, all applicable hospital federal participation requirements and that the following safeguards are in place (Check each item for an affirmative response):

_____ The ASC named above may enroll as a hospital provided that it is not inconsistent with the state's emergency preparedness or pandemic plan.

_____ To the extent not waived, the ASC named above is compliant with the requirements of 42 CFR 482.23 Condition of Participation: Nursing Services. In particular, but not limited to:

- Ensure adequate numbers of licensed registered nurses and other personnel to provide nursing care to all patients as needed
- Provide 24 hour nursing services furnished or supervised by a registered nurse, *when there is a patient in the ASC enrolled as a hospital*
- Ensure drugs and pharmaceuticals are prepared and administered in accordance with Federal and State laws and according to the orders of the practitioner(s) responsible for the patient's care

_____ To the extent not waived, the ASC named above is compliant with the requirements of 42 CFR 482.25 Condition of Participation: Pharmaceutical Services. In particular, but not limited to:

- Provide pharmaceutical services that meet the needs of the patients
- Have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision
- Provide a full-time, part-time or consultant pharmacist who is responsible for all activities of the pharmacy services
- Provide an adequate number of personnel to ensure high quality pharmaceutical services, including emergency services
- Ensure Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse and Prevention and Control Act of 1970 are kept locked within a secure area

_____ To the extent not waived, the ASC named above is compliant with the requirements of 42 CFR 482.42 Condition of Participation: Infection Control and Antibiotic Stewardship Programs. In particular, but not limited to:

- Appointed a qualified individual as the Infection Preventionist/Infection Control Professional
- Employ methods for preventing and controlling the transmission within the hospital and between other providers
- Create an Infection Control Surveillance plan to control Healthcare Acquired Infections
- Establish a hospital-wide antibiotic stewardship program in accord with national standards

_____ To the extent not waived, the ASC named above is compliant with the requirements of 42 CFR 482.57 Condition of Participation: Respiratory Services. In particular, but not limited to:

- Ensures that a director of respiratory care services who is a doctor of medicine or osteopathy is available on a full or part-time basis to supervise and administer respiratory services
- Ensure an adequate number of qualified respiratory therapists and technicians
- Ensure all respiratory services are delivered in accordance with medical staff directives

Attestation on behalf of the ASC named above by:

Signature _____ Title _____

Printed Name _____ Date _____

** This attestation statement will cease to be in effect and the associated hospital CCN will be terminated when the Secretary of the Department of Health and Human Services determines there is no longer a Public Health Emergency due to COVID-19. At that time, CMS will send public notice that this attestation has ceased to be effective via its website.*

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