KUTAKROCK

COVID-19
SPECIAL PUBLICATION

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Increasing the Healthcare System's Capacity to Provide Hospital Services

On Monday, March 30, 2020, the Centers for Medicare and Medicaid Services ("CMS") issued a number of blanket waivers and an interim final rule entitled "Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" that temporarily relax a variety of regulations in an effort to allow the United States healthcare system to prepare for and address patient surges during the COVID-19 public health emergency ("PHE").

An important component of this effort is CMS's "Hospital Without Walls" initiative, which provides hospitals with flexibility to utilize non-traditional sites to provide hospital services, such as room and board, nursing, and other hospital services. Under this initiative, CMS is waiving certain requirements relating to the physical environment under the Medicare Conditions of Participation for hospitals (the "COPs") to allow for flexibility during hospital surges and will permit non-hospital buildings/space to be used for hospital services, provided that the location is approved by the applicable state authority. Further, CMS is waiving the provider-based department requirements at 42 CFR §413.65, which will allow hospitals to establish and operate as part of the hospital any location meeting the COPs in operation during the PHE and to change the status of their current provider-based department locations to the extent necessary to address the needs of hospital patients as part of the applicable state or local pandemic plan. Finally, CMS is offering some additional flexibilities to furnish inpatient services under arrangements.

In addition to other non-traditional hospital sites (e.g., hotels and community facilities), the CMS waivers specifically contemplate the use of ambulatory surgery center ("ASC") facilities as expansion sites, as such facilities offer the advantage of already being set up to provide healthcare services. There are three mechanisms to use ASC facilities as expansion sites: (1) an ASC can lease (or license) its facility, equipment, and/or staff to a hospital, with the hospital operating the ASC premises as an additional site or campus of the hospital; (2) the ASC can provide services to a hospital on an "under arrangements" basis (as explained below); and (3) the ASC can enroll with Medicare and operate as a new hospital (with or without the ownership or involvement of an existing hospital).

This alert discusses various scenarios made possible by the recent CMS blanket waivers and interim final rule that would result in increased capacity across the United States healthcare system to offer hospital services and the regulatory, financial, and logistical considerations associated with each.

Option 1: Hospital Use of Non-Traditional Site

A hospital can establish and operate as part of the hospital a hospital location in a non-traditional site, such as a hotel, dormitory, or community facility, including, but not limited to, a convention center or outside sports arena.

1. Requirements:

    a. Lease/License Agreement – The parties would need to enter into a written lease or license agreement, setting forth the compensation the hospital will pay for use of the facility, if any.

    b. Waiver of State Licensure Requirements – The hospital would need to seek a waiver of state requirements that the non-traditional site be licensed as part of the hospital during the PHE. Through the blanket waivers, Medicare has already approved the hospital using a non-hospital location to provide hospital services during the PHE, as long as the space is approved by the state. We anticipate that state licensing authorities will react quickly to facilitate this type of arrangement if consistent with the state's emergency preparedness plan. Several states have already issued guidance on these licensure issues.

    c. Securing Equipment and Staff – The hospital would need to secure additional staff and equipment to facilitate the use of non-healthcare space for the provision of hospital services.

d. Conversion of Physical Space – Although CMS is waiving certain COPs relating to the physical environment of hospital space, non-traditional sites will not have basic safety features necessary to treat infectious patients, such as negative pressure, sealed rooms, appropriate electrical supply and backup generators, HEPA filtering systems, and infectious waste disposal. The CARES Act appropriates $100 billion dollars to the Public Health and Social Services Emergency Fund to reimburse healthcare providers for healthcare-related expenses, including the building or construction of temporary structures and leasing of properties. However, given the uncertainty associated with how these funds will be distributed to healthcare providers, both the cost and logistics of these conversions could present a complicating factor associated with the use of non-traditional sites by hospitals.

2. Financial Considerations:

a. The hospital would bill for services provided at the non-traditional site and bear the cost of additional staff and equipment necessary to provide hospital services.

b. Compensation from the hospital to the non-traditional site would not be subject to the Stark Law or Anti-Kickback Statute, unless there is physician ownership of the non-traditional site or if the non-traditional site has the ability to refer patients to the hospital for healthcare services, which is unlikely.[1]

Option 2: Hospital Lease/License of ASC Facility, Equipment, and/or Staff

A hospital can enter into a lease or license arrangement with an ASC pursuant to which the hospital would have use of some or all of the ASC facility, equipment, and/or staff and could operate the ASC facility as part of the hospital. The hospital would compensate the ASC for its use of the ASC space, equipment, and/or staff.

1. Requirements:

a. Lease/License Agreement – The parties would need to enter into a written lease or license agreement, setting forth the space, equipment and/or staff being leased/licensed and the fees that are owed to the ASC for such space, equipment and/or staff.

b. Waiver of Provider-Based Requirements – CMS has waived the provider-based rule requirements applying to provider-based departments during the PHE. Therefore, it is not necessary to meet the provider-based requirements or obtain a waiver of such requirements for hospital services provided in an ASC facility setting under this option.

c. Waiver of State Licensure Requirements – The ASC would need to seek a waiver from the state licensing authority of any requirement that the ASC facility be in operation as an ASC. Likewise, the hospital would need to seek a waiver of state requirements that the ASC facility be licensed as a hospital. We anticipate that state licensing authorities will react quickly to facilitate these arrangements if consistent with the state's emergency preparedness plan. As discussed in paragraph 1.b. of Option 1, Medicare has approved hospital use of a non-hospital location (including an ASC) to provide hospital services, provided that the space is approved by the state.

2. Financial Considerations:

a. The hospital would bill for services provided at the ASC facility and pay the ASC for the use of space, equipment, and/or staff being leased/licensed by the hospital.

[1] To the extent that a non-traditional site is physician-owned, we note that, as discussed below, the blanket waivers issued by CMS include certain waivers of the Stark Law that could apply to the compensation arrangement between the hospital and non-traditional site, depending on the terms and structure of the arrangement. In addition, the Office of Inspector General, the federal agency responsible for administrative enforcement of the Anti-Kickback Statute, has stated that a transaction between a hospital and a vendor who delivers services and supplies that has as its primary purpose the delivery of supplies or services necessary to the hospital's response to the PHE will not be subject to prosecution or sanctions under the Anti-Kickback Statute.

b. A lease/license arrangement would generally be more advantageous financially to the hospital than to the ASC, at least when compared to the other ASC options discussed below.

i. The hospital would be entitled to all fees collected for hospital services provided by the hospital in the ASC facility, but the lease/license arrangement would provide a stream of revenue to the ASC that would cover some of its fixed costs.

ii. The lease or license fee would need to be fair market value. While the Stark Law blanket waivers provide flexibility with respect to the fair market value requirement of various direct Stark Law exceptions (i.e., those applying to arrangements with physicians, their practices, and their immediate family members), the blanket waivers do not apply to indirect arrangements such as those with ASCs; nor has the OIG issued blanket waivers for purposes of the Anti-Kickback Statute. However, the OIG has stated that with respect to conduct during the PHE that may be subject to OIG administrative enforcement, OIG will "carefully consider the context and intent of the parties when assessing whether to proceed with any enforcement action."[2] CMS similarly has indicated that COVID-19 related requests for individual Stark Law waivers will receive expeditious treatment. Unless an entity has received comfort from the OIG and CMS, the arrangements should be consistent with fair market value. Given the circumstances and need for the parties to quickly enter into these arrangements, it may not be possible to obtain an independent valuation to confirm the fair market value of an arrangement. However, the parties should document the basis for the lease or license fee as evidence that the fee is fair market value, as well as the intent of the parties in undertaking the arrangement.

Option 3: ASC Provides Services to Hospital "Under Arrangements"

During the PHE, a hospital can contract with the ASC for the ASC to provide hospital services, including "routine" hospital services, "under arrangements" to the hospital. These "under arrangement" services are considered as being provided by the hospital, allowing the hospital to bill for the services. The hospital would be required to exercise sufficient control and responsibility over the use of hospital resources in treating patients through an "under arrangements" arrangement with an ASC.

1. Requirements:

a. Services Agreement – The parties would need to enter into a services agreement, setting forth the terms and conditions under which the ASC will provide services to the hospital "under arrangements" and the fees that are owed to the ASC for its provision of such services.

b. Waiver of Provider-Based Requirements – As described above, CMS has waived the provider-based rule requirements applying to provider-based departments during the PHE. Therefore, it is not necessary to meet the provider-based requirements or obtain a waiver of such requirements if the ASC does not meet the provider-based requirements that usually apply in order for services provided outside the primary hospital location to be considered hospital services.

c. Waiver of State License Requirements – Both the ASC and the hospital would need to seek permission from state licensing authorities for the ASC to provide hospital services and for the hospital to obtain some of its services through an ASC. Through the blanket waivers, Medicare has already approved the hospital using a non-hospital location (including an ASC) to provide hospital services, as long as the space is approved by the state. We anticipate that state licensing authorities will react quickly to facilitate these types of arrangements.

[2] https://oig.hhs.gov/coronavirus/letter-grimm-03302020.asp.

2. Financial Considerations:

   a. The hospital would bill for the services provided as hospital services and would be reimbursed for such services. The parties would need to agree upon compensation to be paid by the hospital to the ASC for the "under arrangements" services provided by the ASC.

   b. Assuming that the physician owners of the ASC make referrals of designated health services ("DHS") services (including inpatient and outpatient hospital services) to the hospital, the compensation paid by the hospital to the ASC for the "under arrangements" services would need to comply with the Stark Law regulations regarding indirect compensation arrangements; i.e., the compensation could not vary with or take into account the volume or value of referrals of other business generated by the physician owners for the hospital, which would prevent use of a "unit of service-based" or percentage-based methodology. In addition, the ASC would also need to seek a Stark Law waiver from CMS protecting the distributions the physicians will receive as owners in the ASC, given that there is likely significant risk that the ASC would be seen as "performing" the inpatient or outpatient hospital services that it is providing "under arrangements" to the hospital.[3] Finally, for the reasons discussed in paragraph 2.b.ii. above under Option 2, the services fee payable to the ASC under the services agreement would need to be fair market value. We recommend that the parties follow the principles outlined in paragraph 2.b.ii. of Option 2 for determining and documenting the fair market value of the services fee.

Option 4: ASC Enrolls as a Hospital

CMS is permitting currently enrolled ASCs to temporarily (during the PHE) enroll with Medicare as a hospital, provide inpatient and outpatient hospital services, and bill as Part A providers.[4] However, it is uncertain whether Medicaid or commercial payors will recognize ASCs as hospitals and reimburse them for providing hospital services.

1. Requirements:

   a. State License Requirements – The ASC would need to obtain a state license to operate as a hospital and satisfy any certificate of need requirements or obtain a waiver for both. Again, we anticipate that state licensing authorities will react quickly to requests for ASCs to be licensed as hospitals during the PHE.

   b. Stark Law Requirements – There is no requirement to obtain a waiver, if one would be otherwise required[5], for physician ownership of an ASC enrolled as a hospital and providing DHS to satisfy an exception to the Stark Law, as the blanket waiver issued by CMS implicitly permits physician owners of the hospital to receive remuneration as a result of DHS provided at the ASC.

   c. Medicare Enrollment Requirements – The ASC would need to enroll with Medicare as a hospital. This is a temporary enrollment that will end when the PHE ends. To enroll, the ASC should notify the Medicare Administrative Contractor (MAC) of its intent by calling the MAC's COVID-19 Provider Enrollment Hotline, and then complete and sign an attestation form specific to the COVID-19 PHE, which is attached as Attachment 1 to this Alert. Any ASC that is enrolled as a hospital will have its ASC billing privileges deactivated while it is enrolled as a hospital. More information about the enrollment process can be found here.

[3] This is only the case if the physician-owners of the ASC make referrals of the services to be performed "under arrangements." Otherwise, there would not be an indirect financial relationship between the hospital and the physician-owners of the ASC, the Stark Law would not be implicated, and no Stark Law waiver would be necessary.

[4] CMS has also stated that under the "Hospital Without Walls" initiative, other interested entities, such as freestanding emergency departments, can pursue enrolling in Medicare as an ambulatory surgery center and then convert the enrollment to a hospital during the PHE. Given the potential time associated with two conversions, it is not clear whether this would be a viable alternative for freestanding emergency departments.

[5] Under normal circumstances, a physician who makes referrals of DHS to an entity providing those services (a "DHS Entity") cannot have a financial relationship with the DHS entity unless the financial relationship satisfies the requirements for an exception to the Stark Law. In the current situation, depending upon the case mix of the ASC-enrolled hospital and the specialties of the ASC physician owners, it is possible that the physician owners of the ASC would not make referrals of DHS to the ASC-enrolled hospital. If so, then the Stark Law would not be implicated by the physician-owned ASC-enrolled hospital, even in the absence of CMS's blanket waiver.

The MAC will review and forward the signed attestation statement to the CMS Regional Office ("RO"), which will review all survey activity of the ASC during the previous three years (recertification and/or complaint). 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 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), and send a tie-in notice as a hospital to the MAC. The effective date of the ASC's enrollment as a hospital is the date when the attestation was accepted by the MAC. If IJ-level deficiencies are found within the last year and enforcement activities are currently ongoing, then the RO will not accept the attestation and notify the MAC of denial of temporary hospital enrollment.

While an onsite survey is not required for RO approval for an ASC to enroll as a hospital, the 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,[6] and the availability of personal protective equipment as needed.

When the Secretary of the U.S. Department of Health and Human Services determiners that the PHE has ended, the RO will terminate the ASC's hospital CCN and send a tie-out notice to the MAC. The MAC will deactivate the ASC's hospital billing privileges and reinstate the ASC's ASC billing privileges effective on the date the ASC's hospital status is terminated. If a hospital-enrolled ASC desires to revert back to an ASC prior to the end of the PHE, the ASC must notify its MAC in writing.

d. Compliance with Hospital Conditions of Participation – An ASC-enrolled hospital is required to meet the COPs, to the extent not waived, when enrolled as a hospital, though it would not be required to meet the Medicare ASC conditions for coverage ("CFC") while it was enrolled as a hospital.

A summary of the hospital COPs, as well as those COPs that have been waived in the context of the PHE, is set forth in Attachment 2. As seen in the attestation form in Attachment 1, the ASC is required to attest to its compliance with non-waived hospital COPs at the time of the ASC's enrollment as a hospital, with particular emphasis on the COPs relating to (i) nursing services, (ii) pharmaceutical services, (iii) infection control and antibiotic stewardship programs, and (iv) respiratory services.

Upon the ASC's temporary hospital enrollment ending, the ASC would need to come back into compliance with all applicable ASC federal participation requirements, including the CFCs.

2. Financial Considerations: The ASC would bill Medicare for the hospital service provided by the ASC. As mentioned above, it is not clear whether other payors would recognize the ASC as a hospital provider during the PHE. The ASC would need to engage in discussions with other payors to determine whether the payors would recognize the ASC's temporary hospital status. Financial benefit to an existing hospital would be limited to its share of ASC profits as an owner of the ASC, if applicable, or payment for any services it might provide to the ASC. The ASC would also need to consider the cost of any changes that might be needed to facilitate provision of hospital services and whether those costs can be recovered.

Kutak Rock attorneys are actively engaged in monitoring the legislative and regulatory changes undertaken in response to COVID-19 pandemic. Other client alerts and special publications relating to COVID-19 can be accessed on Kutak Rock's COVID-19 Legal Resource Portal. If you are interested in determining whether the scenarios discussed in this Alert are available to you, please contact a member of our national Healthcare practice group.

[6] The infection control survey will be based on the criteria set forth in the CMS Memo QSO-20-20-All. Any need for enforcement actions as a result of the survey would follow what is outlined in the CMS Memo or any subsequent updates to the CMS Memo.

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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
- 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.*

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.

ATTACHMENT 2
Conditions of Participation for ASC-Enrolled Hospital

COP	COP Subject	Applicable Section 1135 Waivers	Comments
§482.11	Compliance with Federal, State and Local Laws	No applicable waivers.	ASC-enrolled hospitals would need to meet all COP requirements.
§482.12	Governing Body	Telemedicine. CMS is waiving the provisions related to telemedicine at 42 CFR §482.12(a) (8)–(9) for hospitals, making it easier for telemedicine services to be furnished to the hospital's patients through an agreement with an off-site hospital. This allows for increased access to necessary care for hospital patients, including access to specialty care. Physician Services. CMS is waiving requirements under 42 CFR §482.12(c)(1)–(2) and §482.12(c)(4), which requires that Medicare patients be under the care of a physician. This waiver may be implemented so long as it is not inconsistent with a state's emergency preparedness or pandemic plan. This allows hospitals to use other practitioners to the fullest extent possible. Written Policies and Procedures for Appraisal of Emergencies at Off Campus Hospital Departments. CMS is waiving 42 CFR §482.12(f)(3), emergency services, with respect to surge facilities only, such that written policies and procedures for staff to use when evaluating emergencies are not required for surge facilities. This removes the burden on facilities to develop and establish additional policies and procedures at their surge facilities or surge sites related to the assessment, initial treatment and referral of patients. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.	ASC-enrolled hospitals will need to meet all non-waived COP requirements.
§482.13	Patient's Rights	Reporting Requirements: CMS is waiving the requirements at 42 CFR §482.13(g) (1)(i)-(ii), which require that hospitals report patients in an intensive care unit whose death is caused by their disease, but who required soft wrist restraints to prevent pulling tubes/IVs, no later than the close of business on the next business day. Patient Rights: Hospitals that are located in a state which has widespread confirmed cases (i.e., 51 or more confirmed cases*) as updated on the CDC website, would not be required to meet the following requirements: - §482.13(d)(2) - With respect to timeframes in providing a copy of a medical record. - §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. - §482.13(e)(1)(ii) - Regarding seclusion	ASC-enrolled hospitals will need to meet all non-waived COP requirements.
§482.15	Emergency Preparedness	Emergency Preparedness Policies and Procedures:	ASC-enrolled hospitals will need to meet all non-waived COP requirements.

COP	COP Subject	Applicable Section 1135 Waivers	Comments
		- CMS is waiving 42 CFR §482.15(b), which requires the hospital to develop and implement emergency preparedness policies and procedures. - CMS is waiving §482.15(c)(1)–(5), which requires that the emergency preparedness communication plans for hospitals to contain specified elements with respect to the surge site. The requirement under the communication plan requires hospitals to have specific contact information for staff, entities providing services under arrangement, patients' physicians, other hospitals and CAHs, and volunteers. This would not be an expectation for the surge site. This waiver removes the burden on facilities to establish these policies and procedures for their surge facilities or surge sites.	
§482.21	Quality Assessment and Performance Improvement Program	Quality Assessment and Performance Improvement Program: CMS is waiving 42 CFR §482.21(a)–(d) and (f)), which provide details on the scope of the program, the incorporation, and setting priorities for the program's performance improvement activities, and integrated Quality Assurance & Performance Improvement programs (for hospitals that are part of a hospital system). These flexibilities, which apply to both hospitals, may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. We expect any improvements to the plan to focus on the Public Health Emergency (PHE). While this waiver decreases burden associated with the development of a hospital QAPI program, the requirement that hospitals maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program will remain.	ASC-enrolled hospitals will need to meet all non-waived COP requirements.
§482.22	Medical staff	Medical Staff: - CMS is waiving requirements under 42 CFR §482.22(a)(1)-(4) to allow for physicians whose privileges will expire to continue practicing at the hospital and for new physicians to be able to practice before full medical staff/governing body review and approval to address workforce concerns related to COVID-19. - CMS is waiving §482.22(a) (1)-(4) regarding details of the credentialing and privileging process.	ASC-enrolled hospitals will need to meet all non-waived COP requirements.

§482.23	Nursing Services	Verbal Orders: CMS is waiving the requirements of 42 CFR §482.23 and §482.24 to provide additional flexibility related to verbal orders where readback verification is required, but authentication may occur later than 48 hours. This will allow more efficient treatment of patients in surge situations. 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. Nursing Services: - CMS is waiving the requirement at 42 CFR §482.23(b)(4), which requires the nursing staff to develop and keep current a nursing care plan for each patient - CMS is waiving the requirement at §482.23(b)(7), which requires the hospital to have policies and procedures in place establishing which outpatient departments are not required to have a registered nurse present. These waivers allow nurses increased time to meet the clinical care needs of each patient and allows for the provision of nursing care to an increased number of patients. In addition, we expect that hospitals will need relief for the provision of inpatient services and as a result, the requirement to establish nursing-related policies and procedures for outpatient departments is likely of lower priority. These flexibilities apply to both hospitals and CAHs §485.635(d)(4) and may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.	ASC-enrolled hospitals will need to meet all non-waived COP requirements. In addition, ASC-enrolled hospitals are required to attest to the following with respect to this COP: _____ 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 - 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
§482.24	Medical Record Services	Verbal Orders: CMS is waiving the requirements of 42 CFR §482.23 and §482.24 to provide additional flexibility related to verbal orders where readback verification is required, but authentication may occur later than 48 hours. This will allow more efficient treatment of patients in surge situations. Specifically, the following requirements are waived: - §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). Medical Records: - CMS is waiving requirements under 42 CFR §482.24(a) through (c), which cover the subjects of the organization and staffing of the medical records department, requirements for the form and content of the medical record, and record retention requirements, and these flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. - CMS is waiving §482.24(c)(4)(viii) related to medical records to allow flexibility in completion of medical records within 30 days following discharge from a hospital. This flexibility will allow clinicians to focus on the patient care at the bedside during the pandemic.	ASC-enrolled hospitals will need to meet all non-waived COP requirements.

§482.25	Pharmaceutical Services	Sterile Compounding. CMS is waiving requirements at 42 CFR §482.25(b)(1) 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. CMS will not review the use and storage of face masks under these requirements.	ASC-enrolled hospitals will need to meet all non-waived COP requirements. In addition, ASC-enrolled hospitals are required to attest to the following with respect to this COP: _____ 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
§482.26	Radiologic Services	No applicable waivers.	ASC-enrolled hospitals will need to meet all COP requirements.
§482.27	Laboratory Services	No applicable waivers.	ASC-enrolled hospitals will need to meet all non-waived COP requirements.
§482.28	Food and Dietetic Services	Food and Dietetic Services: CMS is waiving the requirement at paragraph 42 CFR §482.28(b) (3), which requires providers to have a current therapeutic diet manual approved by the dietitian and medical staff readily available to all medical, nursing, and food service personnel. Such manuals would not need to be maintained at surge capacity sites. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. Removing these administrative requirements will allow hospitals to focus more resources on providing direct patient care.	ASC-enrolled hospitals will need to meet all non-waived COP requirements.

§482.30	Utilization Review	Utilization Review. - CMS is waiving certain requirements under 42 CFR §482.1(a)(3) and 42 CFR §482.30 which address the statutory basis for hospitals and includes the requirement that hospitals participating in Medicare and Medicaid must have a utilization review plan that meets specified requirements. - CMS is waiving the entire utilization review condition of participation Utilization Review (UR) at §482.30, which requires that a hospital must have a UR plan with a UR committee that provides for a review of services furnished to Medicare and Medicaid beneficiaries to evaluate the medical necessity of the admission, duration of stay, and services provided. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. Removing these administrative requirements will allow hospitals to focus more resources on providing direct patient care.	ASC-enrolled hospitals will need to meet all non-waived COP requirements.
§482.41	Physical Environment	Physical Environment. CMS is waiving certain requirements under the Medicare conditions of participation at 42 CFR §482.41 to allow for flexibilities during hospital, 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 that safety and comfort for patients and staff are sufficiently addressed) and so long as it is not inconsistent with a state's emergency preparedness or pandemic plan. This allows for increased capacity and promotes appropriate cohorting of COVID-19 patients. Temporary Expansion Locations: For the duration of the PHE related to COVID-19, CMS is waiving certain requirements under the Medicare conditions of participation at 42 CFR §482.41 (as noted elsewhere in this waiver document) and the provider-based department requirements at §413.65 to allow hospitals to establish and operate as part of the hospital any location meeting those conditions of participation for hospitals that continue to apply during the PHE. This waiver also allows hospitals to change the status of their current provider-based department locations to the extent necessary to address the needs of hospital patients as part of the state or local pandemic plan. This extends to any entity operating as a hospital (whether a current hospital establishing a new location or an Ambulatory Surgical Center (ASC) enrolling as a hospital during the PHE pursuant to a streamlined enrollment and survey and certification process) so long as the relevant location meets the conditions of participation and other requirements not waived by CMS. This waiver will enable hospitals to meet the needs of Medicare beneficiaries.	ASC-enrolled hospitals will not need to meet these COP requirements, as the entire COP has been waived with respect to surge sites.

§482.42	Infection Prevention and Control and Antibiotic Stewardship Programs	No applicable waivers.	ASC-enrolled hospitals will need to meet all non-waived COP requirements. In addition, ASC-enrolled hospitals are required to attest to the following with respect to this COP: _____ 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

§482.43	Discharge Planning	<u>Detailed Information Sharing for Discharge Planning for Hospitals</u>: CMS is waiving the requirement 42 CFR §482.43(a)(8) to provide detailed information regarding discharge planning, described below: - The hospital 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, home health agency (HHA), skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), and long-term care hospital (LTCH) quality measures and resource use measures. The hospital must ensure that the post-acute care data on quality measures and resource use measures is relevant and applicable to the patient's goals of care and treatment preferences. - CMS is maintaining the discharge planning requirements that ensure a patient is discharged to an appropriate setting with the necessary medical information and goals of care as described in 42 CFR §482.43(a)(1)-(7) and (b). <u>Limiting Detailed Discharge Planning for Hospitals</u>: - - CMS is waiving all the requirements and subparts at 42 CFR §482.43(c) 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 maintaining the discharge planning requirements that ensure a patient is discharged to an appropriate setting with the necessary medical information and goals of care as described in 42 CFR §482.43(a)(1)-(7) and (b). - CMS is waiving the more detailed requirement that hospitals ensure those patients discharged home and referred for HHA services, or transferred to a SNF for post-hospital extended care services, or transferred to an IRF or LTCH for specialized hospital services, must: o §482.43(c)(1): Include in the discharge plan a list of HHAs, SNFs, IRFs, or LTCHs that are available to the patient. o §482.43(c)(2): Inform the patient or the patient's representative of their freedom to choose among participating Medicare providers and suppliers of post-discharge services. o §482.43(c)(3): Identify in the discharge plan 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.	ASC-enrolled hospitals will need to meet all non-waived COP requirements.
§482.45	Organ, Tissue and Eye Procurement	No applicable waivers.	Organ, Tissue and Eye Procurement services are optional hospital services. To the extent the service is not provided, the COP requirements related to the service would not be applicable.

§482.51	Surgical Services	No applicable waivers.	Although an optional service, we assume an ASC-enrolled hospital would offer these services. Accordingly, if this assumption is correct, ASC-enrolled hospitals will need to meet all COP requirements.
§482.52	Anesthesia Services	Anesthesia Services: CMS is waiving requirements under 42 CFR §482.52(a)(5) and §416.42 (b)(2) that a certified registered nurse anesthetist (CRNA) is under the supervision of a physician in paragraphs §482.52(a)(5). CRNA supervision will be at the discretion of the hospital and state law. This waiver applies to hospitals and Ambulatory Surgical Centers (ASCs). These waivers will allow CRNAs to function to the fullest extent of their licensure and may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.	Although an optional service, we assume an ASC-enrolled hospital would offer these services. Accordingly, if this assumption is correct, ASC-enrolled hospitals will need to meet all COP requirements.
§482.53	Nuclear Medicine Services	No applicable waivers.	Nuclear Medicine Services are optional hospital services. To the extent the service is not provided, the COP requirements related to the service would not be applicable.
§482.54	Outpatient Services	No applicable waivers.	Although an optional service, we assume an ASC-enrolled hospital would offer these services. Accordingly, if this assumption is correct, ASC-enrolled hospitals will need to meet all COP requirements.
§482.55	Emergency Services	No applicable waivers.	Emergency Services are optional hospital services. To the extent the service is not provided, the COP requirements related to the service would not be applicable.
§482.56	Rehabilitation Services	No applicable waivers.	Rehabilitation Services are optional hospital services. To the extent the service is not provided, the COP requirements related to the service would not be applicable.

§482.57	Respiratory Services	CMS is waiving the requirements at 42 CFR §482.57(b)(1) that require hospitals to designate in writing the personnel qualified to perform specific respiratory care procedures and the amount of supervision required for personnel to carry out specific procedures. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. Not being required to designate these professionals in writing will allow qualified professionals to operate to the fullest extent of their licensure and training in providing patient care.	ASC-enrolled hospitals will need to meet all non-waived COP requirements. In addition, ASC-enrolled hospitals are required to attest to the following with respect to this COP: _____ 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
§482.58	Special Requirements for Hospital Providers of Long-Term Care Services ("Swing-Beds")	No applicable waivers.	Swing-Beds are optional hospital services. To the extent the service is not provided, the COP requirements related to the service would not be applicable.