For COVID-19 legal advice across a spectrum of issues impacting an array of industries and legal areas, our team is available and connected nationally and in the communities in which you operate.

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Polsinelli’s cross-disciplinary COVID-19 blog provides companies tools and information needed to effectively and lawfully protect their employees and business.

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CMS allows Medicare reimbursement for hospital care provided in “temporary expansion sites” or non-traditional patient care areas.

Temporary policy during public health emergency

Raises a variety of legal questions for hospital operational and compliance staff:

- Federal hospital regulations
- State licensure / regulatory issues
- Relationships with outside operators
Coronavirus Public Health Emergency (PHE)
- SSA § 1135(b) allows waiver of certain Medicare & Medicaid rules – including Stark Law.
- Arrangements must comply with applicable law as of end of PHE.

CMS can grant waivers if necessary:
- 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 2019 Novel Coronavirus . . . pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse

Reasons for “Hospital Without Walls” Model

- Adding additional capacity for COVID-19 surge:
  - Dedicated triage and screening areas
  - Modified ICU space
  - Adding specialized units (dedicated respiratory observation, PACU, etc.)

- Allowing geographic separation of non-COVID-19 patients
  - Screening or patient care space
  - May allow restoration of some non-COVID functions

- Relocating hospital operations
  - Ex: Dedicated telehealth space
Figure 1.

Goals of Community Mitigation

1. Delay outbreak peak
2. Decompress peak burden on hospitals/infrastructure
3. Diminish overall cases and health impacts

Daily Cases

Days Since First Case

Pandemic outbreak: No intervention
Pandemic outbreak: With intervention
Recommendations on Adult Elective Surgery and Procedures, issued March 18, 2020

“Limit all non-essential planned surgeries and procedures, including dental, until further notice”
CMS Recommendations (4/7)

<table>
<thead>
<tr>
<th>Tiers</th>
<th>Definition</th>
<th>Locations</th>
<th>Examples</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 1</td>
<td>Low acuity treatment or service</td>
<td>• Medical office</td>
<td>• Routine primary or specialty care</td>
<td>Consider postponing service</td>
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<tr>
<td></td>
<td></td>
<td>• FQHC/RHC</td>
<td>• Preventive care visit/screening</td>
<td>Consider follow-up using telehealth, virtual check-in, or remote monitoring</td>
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<td></td>
<td></td>
<td>• HOPD**</td>
<td>• Annual Wellness or Welcome to Medicare Initial Preventive Visit</td>
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<tr>
<td></td>
<td></td>
<td>• Ambulatory care sites</td>
<td>• Supervised exercise therapy</td>
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<td></td>
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<td>• Acupuncture</td>
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<tr>
<td>Tier 2</td>
<td>Intermediate acuity treatment or service</td>
<td>• Medical office</td>
<td>• Pediatric vaccinations</td>
<td>Consider initial evaluation via telehealth; triage to appropriate sites of care as necessary</td>
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<tr>
<td></td>
<td></td>
<td>• FQHC/RHC</td>
<td>• Newborn/early childhood care***</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>• HOPD</td>
<td>• Follow-up visit for management of existing medical or mental/behavioral health condition</td>
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<td></td>
<td></td>
<td>• Ambulatory care sites</td>
<td>• Evaluation of new symptoms in an established patient</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Evaluation of non-urgent symptoms consistent with COVID-19</td>
<td></td>
</tr>
<tr>
<td>Tier 3</td>
<td>High acuity treatment or service</td>
<td>• Medical office</td>
<td>• Evaluation of new symptoms in a new patient</td>
<td>We would not recommend postponing in-person evaluation; consider triage to appropriate facility/level of care as necessary</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• FQHC/RHC</td>
<td>• Evaluation of symptoms consistent with COVID-19, with warning signs including shortness of breath, altered mental status, or other indications of severe disease</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>• HOPD</td>
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<tr>
<td></td>
<td></td>
<td>• Ambulatory care sites</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>• Emergency department</td>
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Non-Emergent, Elective Medical Services, and Treatment Recommendations

“CMS also recognizes the importance of reducing burdens on the existing health system and maintaining services while keeping patients and providers safe.”
Business During the Curve

Cash Flow Challenges

Roller Coaster Ride of Revenue

- **Outpatient volume** has decreased dramatically
- **Approximately 30%** of fee-for-service payments on Medicare inpatient claims are deemed elective
- Severe cash flow impact will be felt **45-50 days** after elective cessation
- **Collectability concerns** on existing patient portion of A/R given economic crisis
- **Looming competition** to capture pent-up demand and funding in aftermath of pandemic
- **Some electives will not return** due to loss in coverage caused by unemployment
“Under federal requirements, hospitals must provide services within their own buildings, raising concerns about capacity for treating COVID-19 patients, especially those requiring ventilator and intensive care. Under CMS’s temporary new rules, hospitals will be able to transfer patients to outside facilities, such as ambulatory surgery centers, inpatient rehabilitation hospitals, hotels, and dormitories, while still receiving hospital payments under Medicare. For example, a healthcare system can use a hotel to take care of patients needing less intensive care while using its inpatient beds for COVID-19 patients.

Ambulatory surgery centers can contract with local healthcare systems to provide hospital services, or they can enroll and bill as hospitals during the emergency declaration as long as they are not inconsistent with their State’s Emergency Preparedness or Pandemic Plan. The new flexibilities will also leverage these types of sites to decant services typically provided by hospitals such as cancer procedures, trauma surgeries, and other essential surgeries.”

- CMS press release announcing waivers
Challenges of Hospitals Without Walls

- Not initially contemplated by state and federal law covering hospital space – has required emergency action.
  - States are allowing different levels of flexibility
- Changes were urgently needed – hospitals’ operational processes may have varied.
- Quickly negotiating leases or other commercial arrangements to use space.
- Long-term needs for space are unclear.
Medicare Conditions of Participation (CoPs)
Inpatient services “under arrangements”
Provider-based regulations
Critical Access Hospitals (CAHs)
Distinct Part Units (DPUs), e.g., psych and rehab
Emergency Medical Treatment and Labor Act (EMTALA)
Provider enrollment
340B drug pricing program
Opportunities to Expand Hospital Space

- Existing hospital space – examples:
  - Convert OR space to ICU or PACU
  - Convert waiting rooms or non-patient care areas to triage, screening, or observation areas for COVID-19 surge
  - DPUs
  - CAHs

- Non-hospital health space (temporary expansion sites) – examples:
  - Ambulatory Surgery Centers (ASCs)
  - Urgent care clinics and freestanding emergency departments (FSEDs)
  - Medical office suites (consider restructuring opportunities)

- Non-health care space
  - Hotels, convention centers
# CMS CoP Waivers

<table>
<thead>
<tr>
<th>What’s Waived</th>
<th>What’s Not Waived</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>42 CFR §482.41 Physical Environment</strong></td>
<td><strong>42 CFR §482.11 Compliance with Federal, State and Local Laws</strong></td>
</tr>
<tr>
<td>Broad waiver but requires state approval to ensure “safety and comfort for patients and staff”</td>
<td>e.g., may require state hospital license</td>
</tr>
<tr>
<td><strong>42 CFR §482.12 Governing Body</strong></td>
<td><strong>42 CFR §482.25 Pharmaceutical Services</strong></td>
</tr>
<tr>
<td>Waives distant site agreement for telemed (a)(8-9), off-campus hospital departments don’t need med staff-approved emergency appraisal/referral policies if surge facility (f)(3), care can be under NPP (c))</td>
<td>Hospital must provide pharmaceutical service that meets patient needs</td>
</tr>
<tr>
<td><strong>42 CFR §482.13 Patient’s Rights</strong></td>
<td><strong>42 CFR §482.26 Radiologic Services</strong></td>
</tr>
<tr>
<td>Certain visitation (h) and seclusion waivers (e)(1)(ii)/(g)(1)(i-ii) waived in states with “widespread confirmed cases”</td>
<td>Hospital must maintain or have available</td>
</tr>
<tr>
<td><strong>42 CFR §482.22 Medical staff</strong></td>
<td><strong>42 CFR §482.27 Laboratory Services</strong></td>
</tr>
<tr>
<td>Broad waiver of privileges requirements including telemedicine (a)(1-4)</td>
<td>Hospital must maintain or have available</td>
</tr>
</tbody>
</table>
CMS CoP Waiver Considerations

- Feasibility of using alternative space on a temporary basis
- Ability to get state approval
  - e.g., what to do when states don’t typically license certain facilities / departments
- Relationship to other waivers (ASCs, telemedicine, etc.)
- Assessing alignment with state emergency preparedness or pandemic plans
Historically, the SSA required “routine services” be provided “in the hospital”
- Routine services include room and board, nursing services, social services, other items ordinarily furnished in the hospital
- Prohibited under arrangements for routine services provided outside of the hospital

Temporary policy change permits under arrangements for routine services during PHE
- *e.g.*, admitting hospital can receive Medicare payment for an inpatient that is moved outside of hospital for routine services at an alternate site
CMS is waiving provider-based department (PBD) requirements at 42 CFR § 413.65

- Requirements include common licensure, clinical and financial integration, public awareness, and distance limitations

- Allows hospitals to:
  - Establish and operate as part of the hospital any location meeting the conditions of participation for hospitals in operation during the PHE
  - Change the status of their current PBD locations to the extent necessary to address patient need as part of the State of local pandemic plan
Provider-Based Department Waiver Considerations

- Do we need a license / state approval?
  - CoPs and related CMS waivers may still mandate state approval
  - What if your state doesn’t typically license / approve these sites (e.g., on-campus PBDs)

- If we make a change to an excepted site under Section 603 of the Bipartisan Budget Act (BBA) of 2015, do we risk losing excepted status?
  - Waivers unclear, and the BBA is a statutory program
  - Relocations/expansions of excepted sites should be done in consultation with regional offices (ROs)

- Will new temporary locations be subject to site neutral payments under Section 603?
  - Maybe, CMS indicated they are considering this issue

- What happens to the site when the PHE ends?
No prospective blanket waivers of 340B rules
  - Must adhere to patient definition and group purchasing organization (GPO) prohibition
  - May wish to seek provider-specific exceptions

Telehealth and 340B
  - Must meet patient definition
  - Document your approach in policies and procedures

Inventory/technology considerations with surge / geographic separation locations
  - Is it possible to track eligible/ineligible patients at temporary sites?
  - Is it worth it? If not, consider whether existing registrations could be a problem.

Office of Pharmacy Affairs Information System (OPAIS) registration logistics
  - Likely expedited review
  - Questions/logistics handled by Apexus
State Regulatory Considerations

- Declaration of State of Emergency
- Hospital Licensure Requirements
- Certificate of Need/Facilities Planning Requirements
- Life Safety Code/Physical Environment Requirements
- Accreditation & Survey Considerations
What do you enroll?
- Any and all locations where hospital is going to provide care (ASCs, PBDs, hotels, etc.)
- Includes temporary Part A “isolation facilities”

How do you enroll a temporary site?
- Part A providers establishing isolation facilities – call Medicare Administrative Contractor (MAC) hotline for temporary privileges
- All others submit via PECOS/855A

Timing
- Clean web applications filed on or after March 1 processed within 7 business days
- What’s the process for unwinding?
1. Allows Medicare-certified ASCs to temporarily enroll as hospitals
   - Other entities, such as FSEDs, can enroll as ASCs and convert to enrollment as hospital

2. To receive temporary billing privileges as a hospital, ASCs should:
   - Call the COVID-19 Provider Enrollment Hotline and notify the MAC that services the ASCs jurisdiction
   - Complete signed attestation statement
   - Cannot be both ASC and hospital simultaneously. ASC billing privileges will be deactivated while enrolled as a hospital.

3. CMS RO will review all survey activity of the ASC from previous 3 years:
   - If no Immediate Jeopardy-level deficiencies were found (or were removed through survey process), then RO will approve attestation, create a new facility profile in ASPEN, and ASC will be assigned a hospital CMS Certification Number.
   - An onsite survey is not required for approval.

4. Effective date of enrollment = date attestation accepted by MAC
Critical Access Hospitals Without Walls and Distinct Part Unit Flexibility

- **CAHs without walls**
  - 42 CFR 485.610(b) rural location requirement waived
  - 42 CFR 485.610(e) off-campus and co-location requirements waived (e.g., can establish provider-based location within 35 miles of another facility)

- **DPUs**
  - General acute patients may be housed in DPUs due to capacity issues
    - Must be billed as general acute with annotation in EMR
  - Psych and rehab DPU patients may be relocated to general acute beds
    - May be billed under IPF PPS/IRF PPS with annotation in EMR
    - Psych relocations require a safety assessment
    - Rehab patients must continue to receive intensive rehab services
Real Estate Considerations

- New opportunities to use space creatively, including non-traditional hospital space.
- Must still comply with CoPs and be clinically appropriate for the services to be provided.
- Consider operational details, such as:
  - Operational capacities of space (e.g., ability to support necessary medical equipment, laundry, restroom/bathing and dining needs)
  - Space to accommodate necessary staff
  - Ability to order and store necessary supplies
  - Ability to estimate necessary term
  - Restrictions in lease (or master lease/mortgage)
- Polsinelli space matching initiative
- Special considerations for physician-owned space
Governmental options:
- CARES Act / PPP
- Disaster loans

Commercial lenders
- Willingness to work with providers
- “Short form” expedited models

Consider accessing or re-allocation existing resources
Telehealth Considerations

- Telehealth is a key component of utilization management
  - Telehealth (waivers allow expanded use)
    - Non-rural originating sites
    - Use of devices with interactive audio/video communications (e.g., smartphones)
    - Billing for telephone-only E&M codes
  - Numerous waivers of face-to-face requirements that appear in statutes/regs/NDCs/LCDs
    - Virtual check-ins
    - E-Visits
- Telehealth operational & reimbursement
“The CPT codes describing E/M services reflect an assumption that the nature of the work involved in evaluation and management visits varies, in part, based on the setting of care and the patient’s status. . . . We expect physicians and other practitioners to use the E/M code that best describes the nature of the care they are providing, regardless of the physical location or status of the patient.”

New abilities to bill E&M codes in hospital settings using telehealth:

- Emergency department
- Observation Initial hospital care and discharge day management
- Initial nursing facility visits and nursing facility discharge day management
- Critical care services
EMTALA requires Medicare-participating hospitals with an emergency department (ED) to:

1. Treat any individual who “comes to” the ED and requests examination or treatment: a medical screening examination (MSE) must be performed to determine if individual has an emergency medical condition (EMC)
   - Screening for possible COVID-19 should be treated as an MSE
   - MSE must be furnished by qualified medical person (QMP) designated by bylaws or policy
   - Individual only must come to hospital property, not a dedicated ED

2. If individual is determined to have EMC, hospital must provide necessary stabilizing treatment within the hospital’s capabilities and capacity, or make an appropriate transfer.
EMTALA COVID-19 Location Options

- Drive-Through Screening (on Hospital Property)
  - Updated CMS guidance: drive-through testing sites for COVID-19 only "do not have EMTALA implications"
  - Should be staffed by persons trained to identify if immediate need for medical treatment (e.g. RN), but not required to be staffed by QMPs. More of a triage process.
  - Still need appropriate protective equipment

- Tent or Alternate Location (on Hospital Campus)
  - Triage before entering the ED to confirm if seeking COVID-19 screening and redirected to alternate location.
  - Governed by EMTALA. Individual considered to have “come to the ED.”
EMTALA COVID-19 Location Options

- **Tent or Alternate Location w Telemedicine Virtual MSE (on Hospital Campus)**
  - Staffed by non-physician QMP with physician (or supervised PA) furnishing the MSE from a remote location.
  - Implement same EMTALA compliance elements as option 2 above.

- **Off-Campus Alternative COVID-19 Screening Site**
  - Permitted under Section 1135 blanket waiver granted by CMS on March 30, 2020
  - NOT governed by EMTALA - May direct individuals who have already “come to the ED” to proceed to an off-campus alternate COVID-19 screening site.
  - Must be “hospital controlled.” If not already a provider-based location, file 855A to advise MAC of new location
  - May not be held out for general emergency screening. Must transfer individual if immediate attention needed.
Other Regulatory & Business Considerations

- Compensation arrangements
  - “Under arrangements” models as alternative
  - Stark Law considerations & blanket waivers
  - Considerations under Anti-Kickback Statute and state laws

- Planning for next phases of COVID-19 recovery:
  - Slow loosening of social distancing rules
  - Likely “pent up demand” of elective cases
What’s Next?

- CMS flexibilities will end once the emergency declaration has ended
  - Provider-based status
  - Waived CoPs
  - “Under arrangements” rules
  - ASC enrollment as hospital
  - Fraud & abuse flexibilities
  - Telehealth flexibility
- May require termination/modification of leases and related agreements on short notice
- Unwind or termination process should be part of planning
- Potential for ongoing need for flexibilities to continue beyond PHE – ex. COVID-19 patient separation
Hospital A is exploring temporary expansion sites in response to COVID-19 surge to address current needs and anticipated spike

Nearby options:

- Skilled Nursing Facility
- Hotel
- ASC
- Parking lot

What issues should Hospital A consider for each potential site?
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