Reopening Hospital Service Lines: A Playbook for Moving Forward

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POLSINELLI

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Introduction

The COVID-19 pandemic has created severe financial and operational difficulties for hospitals. Rapidly responding to a novel pathogen within a declared Public Health Emergency (PHE), while experiencing decreased revenues as a result of closing facilities to non-COVID-19 and non-emergent care are exceptional challenges. Hospital margins are strained due to the cancellation of non-emergent care, reduced patient utilization of healthcare services, and increased expenditures associated with preparation for a surge of COVID-19 cases.

In recognition of the need to preserve hospital capacity, states have prioritized hospitals in efforts to reopen segments of the economy. Many of the state and federal guidelines for reopening or resuming service lines require hospitals to exercise significant judgment in determining when and how to safely reopen and deliver care. Hospitals must consider a variety of legal issues as they slowly return to providing care to substantial numbers of non-COVID-19 patients, while maintaining readiness in the event of additional surges. This Playbook is intended to help hospitals identify issues by illustrating some of the questions that hospital operational, legal, and compliance staff should address as part of a reopening strategy.

Guidelines for Reopening Hospital Service Lines

CMS Phase I Guidance for Reopening Facilities to Non-Emergent Care

On April 19, 2020, the Centers for Medicare and Medicaid Services (CMS) issued new recommendations for hospitals to restart on-site care to patients without COVID-19 symptoms or in need of emergency care, entitled "**Re-opening Facilities to Provide Non-emergent Non-COVID-19 Healthcare: Phase I**" (Phase I Guidance). The Phase I Guidance replaced the prior guidance issued by CMS on April 6, 2020 limiting non-essential medical care, a summary of which is available **here**.

The Phase I Guidance allows hospitals in a state and region to resume non-emergent, in-person care of non-COVID-19 patients if certain "Gating Criteria" are met. These criteria were set out by the Trump Administration on April 16, 2020 as part of its "Guidelines for Opening Up America Again," available **here**. The Gating Criteria provide that a hospital may resume certain non-emergent care (such as certain procedural care (surgeries and procedures), chronic disease management, medical services, and, ultimately, preventive care) if:

There has been a downward trajectory over a 14-day period of reported symptoms of:

- Influenza-like illness, and
  - COVID-19-like syndromic cases;
  - There has been a downward trajectory over a 14-day period of documented COVID-19 cases in the region, or a downward trajectory of positive tests as a percentage of the total tests completed, with the volume of testing remaining flat or increasing;
- Hospitals in the region are able to treat patients without crisis care; and
- There is a robust testing program in place for at-risk healthcare workers, including antibody testing.

While there is a fair amount of discretion left to hospitals in planning the resumption of service lines under the Gating Criteria, the Phase I Guidance does describe a series of recommendations to guide them in that evaluation.

CMS continues to strongly advise hospitals to use alternative care models, such as telehealth, virtual check-ins, and remote monitoring wherever possible and clinically appropriate. Where telehealth modalities are not possible, individual cases should be evaluated for necessity based on clinical needs of the patient and the resources available. Services for high-complexity conditions, chronic disease management, or other high-acuity condition should be prioritized over lower acuity services. Hospitals should also consider the availability and conservation of personal protective equipment (PPE), availability of workforce across the phases of care, facility readiness, medical supply availability, and testing capacity.

The federal government has also made available a COVID-19 Workforce Virtual Toolkit that gathers together various tools and resources from existing CMS and CDC guidance and third-party sources for healthcare providers to use in assessing their response to the COVID-19 emergency, available **here**.

State and Local Guidance

Even where the Gating Criteria are met, hospitals must ensure that the state, county and other applicable local areas where they reside allow for the resumption of non-emergent, clinically-appropriate services, particularly those postponed under the PHE. We recommend working with state, county and other applicable local government entities on the appropriate approach to reopening to ensure that the state and local governments, as well as the local hospitals, have the resources in place to provide non-emergent and non-COVID-19 care in a safe and effective manner, while also maintaining the ability to quickly respond to additional surges in COVID-19 cases, if necessary.

The Phase I Guidance recommends a phased approach and further Gating Criteria at the discretion of the state governors on the statewide or county-by-county level. States have taken a range of actions both in terms of restrictions on non-emergent medical services and in the steps to restart them. These state executive orders and emergency regulations are evolving quickly, and, as such, before proceeding to reopen a service line under the Phase I Guidance, hospitals should review applicable state and local executive orders and emergency regulations, which could impose additional limitations.

For up-to-date information regarding which states have issued executive orders to ease restrictions on non-emergent surgeries and procedures for non-COVID-19 patients, see our COVID-19 Response Team's updated guidance materials **here**.

Third-Party Reopening Tools

In parallel with the rules and guidance described above, many professional medical associations and other third-party organizations have released additional guidance, recommendations, and decision-making tools to assist hospitals in determining when and how to safely restart non-emergent elective surgeries and medical procedures. For example, the joint guidelines issued by the American Hospital Association (AHA), American College of Surgeons (ACS), American Society of Anesthesiologists (ASA), and the Association of periOperative Registered Nurses (AORN) on April 17, 2020 (hereinafter the "Joint Guidelines"), available **here**. The Joint Guidelines are intended to help hospitals assess when, and how, to safely resume elective medical services in light of patient characteristics.

In many aspects, the Joint Guidelines mirror the updated Phase I Guidelines by providing initial threshold criteria for resuming procedures and ongoing considerations for facilities as they resume non-emergent services. They also provide valuable clinical recommendations to assist in the development of a prioritization committee, tools for assessing capacity across the phases of surgical care, policy guidance for testing staff and patients for COVID-19, and social distancing recommendations for staff, patients and visitors.

The ACS has also released guidance on clinical principles and issues for facilities to consider prior to resuming elective surgical care. The University of Chicago similarly published a new clinical scoring system, the Medically Necessary Time-Sensitive (MeNTS) Prioritization, to assist facilities and physicians in prioritizing specific procedures according to patient characteristics (including any known co-morbidities or underlying health issues).

Operational Considerations for Resuming Non-Emergent Care

Availability of PPE, Medical Supplies, and Equipment

As each facility considers whether and how to reopen for the delivery of care beyond treatment of COVID-19 and other emergency services, it must be diligent in tracking and managing its inventory and supply line for PPE, medical supplies and equipment. The CDC and CMS continue to recommend that healthcare providers and staff wear surgical face masks at all times, and that those practitioners and staff involved with procedures involving mucous membranes use appropriate respiratory protection (e.g., N95 masks and face shields). Patients should also wear either a surgical or cloth mask.

COVID-19 remains an active risk, regardless of whether a hospital has treated any COVID-19 cases in its facilities. Careful attention must be paid to ensure adequate PPE, medical supplies and equipment before a hospital resumes any service lines. Hospitals need to ensure they have sufficient stock for any reopened service lines, and for any potential COVID-19 surge. The CDC's website offers a **Personal Protective Equipment Burn Rate Calculator** to help hospitals plan and optimize the use of PPE by calculating estimates of how long a facility's remaining supply of PPE will last based on an average consumption rate. This calculator can also be used to project each facility's future PPE needs. Most projections expect some surge activity as businesses begin to reopen, so hospitals must remain diligent in planning and working with suppliers to ensure sufficient stock of supplies for any service line restorations, while maintaining supplies to address any future surge in COVID-19 cases.

As with the initial COVID-19 outbreak, limited supplies of PPE and other supplies can create concerns that a facility may be unable to protect its staff, which may increase the risk of lawsuits and staff complaints to the Occupational Safety and Health Administration (OSHA). To mitigate this risk, hospitals may consider greater transparency with staff regarding its current stock of PPE, medical supplies and equipment, the hospital's plans to ensure that it will remain stocked, and the facility's plans regarding PPE and supply use and conservation.

Hospitals should also consider drafting clear policies and training for the appropriate staff to address:

- Supply chain management and inventory controls, ensuring sufficient quantities of the appropriate levels of PPE, medical supplies and equipment. This policy should be reviewed and updated as service lines resumes or as surges spike and shrink, and should provide information regarding the use of non-traditional suppliers in the event of a shortage;
- Use and conservation of PPE and other medical supplies, indicating which individuals should use what level PPE and at what times. The level of PPE required may vary depending on the category of practitioner, and the phase of patient care to which they are attending (e.g., pre-op, surgery, post-op, charting and discharge planning). Consider whether to include some reporting mechanism for physicians, practitioners, and staff who believe they are not receiving appropriate protective gear. Hospitals should also assess whether non-PPE barriers and other physician separation practices can be put in place to protect patients and staff.
- Contingency plans if the facility faces shortages of PPE, medical supplies and equipment, including consideration of CDC and FDA guidelines and extended use and limited reuse of certain PPE supplies and equipment, including N95 masks and respirators. The policy should also consider a clear process and timing to reassess whether to curtail or limit non-emergent care in the future if additional surges of COVID-19 cases require the hospital to conserve PPE.

COVID-19 Testing

As hospitals begin to expand services, developing policies and procedures for testing patients and staff for COVID-19 becomes paramount for the safety of all. Despite the need for widespread and accurate testing, testing availability may be limited and must be performed in compliance with applicable federal and state laws. These laws may include FDA authorizations of the testing reagents and materials, CLIA laboratory requirements, and state law requirements for laboratories and practitioners authorized to order testing and collect specimens. Training personnel who will be collecting specimens for testing will be necessary. Hospitals should also develop consent forms and authorizations (considering HIPAA and state law) for the testing and reporting testing results, especially in the context of testing employees.

Some of these policies and procedures may differ depending on the type of testing the hospital conducts. Currently, the FDA has approved many molecular tests developed by manufacturers and laboratories, but far fewer serology tests for antibodies. A few possibilities for rapid point-of-care molecular testing are available, but rapid serology testing for antibodies lags behind in FDA authorizations. The types of testing (i.e., active virus versus antibody) must be considered in light of the purpose, which may be different for patient and staff testing and the availability of the testing. Hospitals should develop policies with flexibility — both with respect to who does the testing (in-house laboratories versus outsourced to other labs), who collects the specimens, and how these testing aspects may change as the testing technology and availability of testing (both the swab kits and the actual lab test) change, including the expanded possibility of point-of-care rapid testing.

Patient Testing

Hospitals should develop a policy for testing patients pre-operatively, considering which patients should be tested, when, and how. CMS guidance provides that all patients should be screened for potential symptoms of COVID-19 prior to entering the non-COVID-care facility. The screening should include, at a minimum, a questionnaire related to symptoms and taking the patient's temperature. Hospitals should generally follow the CDC's testing guidance as it evolves, and prioritize patients for diagnostic testing based on the procedures that pose the highest risk of exposure to patients and staff, which procedures pose the highest risk of post-operative respiratory complications that would be most severe if exposed to COVID-19 and other circumstances that are unique to the hospital's organization and local circumstances. Hospitals may also want to consider implementing a mandatory pre-operative 14-day quarantine period for select or all patients prior to any procedure to minimize the likelihood the patient will present with COVID-19 on the scheduled date of survey.

The policy should address the timing of testing based on the type of test and when results will be available. Hospitals may need to create a protocol for conducting patient testing on a specific date prior to a procedure to ensure results are received on a timely basis. To ensure the continued validity of the result, hospitals may wish to require a post-test quarantine period to reduce the risk of exposure before surgery after the test is conducted. Post-operative testing may be necessary for patients who demonstrate symptoms consistent with COVID-19. Hospitals should implement protocols to monitor symptoms and determine when testing is warranted to rule out the virus and confirm expected post-operative side effects.

How and where the testing is conducted should be a part of the policy. If the hospital conducts the molecular testing in-house and hospital personnel will be responsible for administering the nasopharyngeal swab, the hospital should specify which personnel (by licensure category, in compliance with state law) will conduct the swabbing and where the patients will go for the testing. The policy may also consider whether the testing should be conducted at other locations under contract with another hospital or laboratory. An order for the molecular test should be in place from a licensed practitioner authorized under state law to order the test. The policy should be flexible enough to accommodate new testing options as they evolve and receive FDA authorization, including options for point of care testing that may change the timing and specimen collection requirements for the testing.

Reporting the test results to the patient, the treating/ordering physician and state and federal authorities should be defined in the policy.

Staff Testing

Testing for healthcare workers should implement both screening and testing procedures. CMS guidelines require routine healthcare worker screenings for COVID-19 symptoms. If symptomatic, staff should be tested and quarantined. The organization should decide whether to test symptomatic employees themselves or refer the employee to their PCP for testing. Testing asymptomatic staff should be considered in light of staff and patient safety, with consideration of local physical distancing orders and the possibility that incidence of COVID-19 may increase.

Staff authorizations/consent requirements may be different depending upon the type of testing conducted. Under HIPAA (and possibly state law), workplace surveillance (generally, molecular) versus fitness-for-duty (generally, antibody) testing may alter the type of authorization the hospital should obtain in order to permit the testing and reporting to the necessary hospital personnel. Reporting to state and federal agencies must also be addressed. If staff refuse to consent, additional policies may be necessary to address these situations and how that refusal may alter the hospital's decisions regarding an employee's ability to report to work.

Facility Readiness

As discussed elsewhere, the federal recommendations and state policies often require hospitals to make the final decision of whether they can perform a procedure or surgery. This involves a careful balancing of interests to determine whether the geographic context of the pandemic, patient characteristics, and aspects of each individual facility. Of these factors, the readiness of the facility is the factor most directly under the hospital or health system's control. Facilities should consider the following factors as they decide whether to reopen for elective procedures and, if so, prioritize the procedures they can safely provide.

Clinical Burden

An important consideration for every hospital is ensuring it remains capable of responding to emergent cases and COVID-19 care (including any future surges of cases). In addition to the state and federal guidance described above, hospitals must consider the potential clinical burden to ensure they maintain adequate resources. For example:

- What is the hospital's current inventory of COVID-19 related resources, including intensive care unit beds, PPE, ventilators, and trained staff? What will the facility commit to keep on hand to prepare? Note that some states and municipalities may establish requirements for minimum beds, supplies, space, or staffing.
- What was the clinical burden of any prior surge on the facility, such as overall admissions, inpatient census, intensive care unit census, emergency department throughput, burn rate of PPE, utilization of ventilators, and similar metrics?
- If the facility was required to develop temporary practice locations or make alternative arrangements to care for the number of COVID-19 patients in an earlier surge, does it have ongoing arrangements to care for a similar number of future patients?
- If COVID-19 continues to be present in the community in declining numbers, how will the facility identify and separate COVID-19 patients from uninfected patients?
- What is the predicted clinical burden of COVID-19 in the region under credible models?
- What is the clinical burden of other diseases and chronic conditions in the community, which may be impacted by the lack of preventive care or certain elective procedures?

Establishing Non-COVID-19 Care (NCC) Zones

One key element of CMS's Phase I Guidelines for resuming non-emergent procedures is designing a clear separation between the spaces used to treat COVID-19 patients and "non-COVID-19 care ("NCC") zones." Hospitals can accomplish this in a variety of ways, including by repurposing existing clinical care areas.

Hospitals may wish to move many COVID-19 cases (particularly those with low acuity) to space that is geographically separated from NCC Zones. This might involve the use of non-traditional clinical care areas (such as lobbies, hallways, waiting rooms, cafeteria space, etc…) under CMS's waiver of the rules on provider-based space. It also might involve establishing a "hospital without walls" so that COVID-19 patients who do not require intensive care may be triaged and treated in a location off the hospital's campus.

Hospitals should consider the following questions to determine appropriate locations for dedicated COVID-19 care space:

- Does the hospital have a screening and triage area established a sufficient distance from the main hospital facilities to accommodate the geographic separation of COVID-19 and non-COVID-19 patients?
- Does the hospital have available space that is not currently used for direct patient care that can be converted into COVID-19 care space without significantly impacting other hospital operations?
- Does the proposed on-campus clinical space have adequate separation from locations used to care for other patients, so that the hospital can implement sufficient infection control measures?
- To the extent the hospital is using temporary or makeshift space to house COVID-19 patients, does it have a longer-term plan in place to build or secure more permanent space to handle future surges?
- Is the hospital's use of this space consistent with the state's emergency preparedness or pandemic control plan?

Strategies for Cohorting and Physical Separation

Under typical CMS rules, a hospital has limited ability to bill Medicare for services provided in locations off its campus. Under typical rules, a hospital may bill for services provided off-campus if the location meets the requirements for being treated as a "provider-based" department of the hospital, which further requires the off-campus location to comply with all of the Medicare Conditions of Participation. CMS has waived the provider-based requirements and some of the Conditions of Participation for the duration of the COVID-19 PHE. This allows hospitals to build "temporary expansion sites" off the hospital's campus, or "alternative care units" in non-traditional parts of the hospital's campus.

In addition, CMS has changed the Medicare enrollment rules for certain special categories of providers including ambulatory surgical centers (ASCs) and freestanding emergency departments (freestanding EDs). CMS has issued new rules allowing these entities to re-enroll as hospitals for the period of the PHE (even if they have physician ownership). CMS has also changed certain rules so that hospitals can enter into relationships "under arrangements" with other providers to delegate care including routine hospital services (e.g., room and board) as well as surgical services.

CMS's waiver of these Medicare rules will not directly impact the policies of state Medicaid programs or commercial plans; hospitals will still need to comply with these. CMS's policies may be persuasive to other payors, however. Hospitals should be aware that most of the flexibilities are only allowed to the extent they are consistent with the state's emergency preparedness or Pandemic Response Plan, and only during the PHE.

Hospitals may wish to consider the following questions as they consider implementing a "hospital without walls" strategy:

- Does the hospital have relationships with existing ASCs, skilled nursing facilities, or other providers who may have available capacity to provide aspects of COVID-19 care or establish NCC Zones?
- Can the hospital effectively exert operational control and maintain compliance with Medicare CoPs over space off the hospital's campus (and potentially operated by other entities)?
- How will the hospital develop an equitable and compliant model for allocating expenses and operational responsibilities across the relevant entities?
- Does the hospital have a plan for the eventual unwinding of the relationship at the end of the PHE?

Long-Term Space for Treating Surges and to Isolate Patients with COVID-19

Following the initial surge, hospitals should consider the best way to transition existing NCC Zones or COVID-19 zones to more stable long-term leases or licenses to use space. This should include formalizing arrangements to use isolation space for COVID-19 patients and develop NCC Zones, as well as developing centralized screening and triage areas for patients and staff.

Hospitals may wish to consider the following questions:

- What kinds of commercial arrangements are optimal to support longer-term space use (e.g., a lease, sublease

or leaseback arrangement, license to use space, purchase of new property)?

- Does the hospital's arrangements with other entities properly account for anticipated legal changes in the location of services when the PHE waiver flexibilities terminate?
- If expansion space will be integrated into the hospital's operations permanently (or for the foreseeable future) what kinds of changes are required to the hospital's operational processes to account for this space?

Infrastructure Investment Choices Considering Role as Part of National Defense; Not Just Cost-Effective Care

In the longer term, hospital may be called upon to make infrastructure investments that benefit a regional or national COVID-19 response, even if these investments may not directly benefit the hospital. This raises a number of legal questions, particularly if the services may reflect in-kind remuneration under healthcare fraud and abuse laws.

- Can the hospital support the creation of healthcare infrastructure to support the national COVID-19 response? These could include a COVID-19 data registry, investment in syndromic surveillance, resources for contact tracing for COVID-19 cases, a regional triage and patient screening strategy, developing mature networks to purchase PPE and other supplies, etc.
- How will this support be offered? For example, will it solely be maintained by the hospital or will it be part of a regional collaborative of multiple hospitals, non-hospital healthcare providers (e.g., large physician practices), and other non-healthcare entities (e.g., state or municipal governments)?
- If the hospital is providing the items or services for free or at a discount to referral sources, will it comply with the Stark Law, Anti-Kickback Statute, and similar fraud and abuse laws?
- Is the hospital required to undertake certain activities that may otherwise be economically inefficient due to professional liability obligations such as maintaining separate and underutilized space for COVID-19 patients in the event of a potential surge?

Continued Use of Telehealth

As hospitals consider reopening their non- emergency service lines, including elective surgeries and procedures, hospital should keep in mind that, for the duration of the PHE, CMS has afforded key flexibilities to Medicare's reimbursement rules that allow hospitals to furnish chronic disease care and preventive care through telehealth. In fact, CMS strongly encourages "maximum use of all telehealth modalities."

CMS has issued blanket waivers to allow beneficiaries to receive telehealth services anywhere, including in their homes (not limited to the enumerated origination sites), and has issued over 80 additional, though temporary, E&M CPT codes, including some that allow for phone only communications (not the otherwise required audio AND video telecommunications). Also, CMS has expanded its application of remote physiologic (RPM) services (CPT codes 99457 and 99458) to new patients, clarifying that RPM services may be used to manage care for patients with chronic and acute disease. Further, CMS has allowed hospitals to conduct "direct supervision" of clinical staff interacting with their patients via real-time interactive audio and video technology where deemed clinically appropriate by that hospital.

State requirements are not waived by CMS's programs waivers — **hospitals must comply** with state specific telemedicine requirements.

Finally, hospitals must be aware that many of CMS's flexibilities with regard to telehealth are likely to end with the PHE and, at this time, it is impossible to predict which ones.

Workforce Considerations

As hospitals resume clinical service lines that have been closed or severely restricted during the pandemic, they must plan carefully to meet the "triple challenge": a staged return to normal operations; continued treatment of pandemic victims and readiness for additional surges of pandemic patients. To meet the triple challenge, hospitals will need to carefully consider what existing safeguards and protections implemented as part of their Pandemic Response Plan should continue unchanged; what should be expanded to encompass returning workforce members; and what should be modified in

response to the changing environment and patient preferences for how they want to receive care (such as continued virtual delivery of certain services even if they can be provided face-to-face). Success in the face of these challenges will require clear communication and partnership with hospital employees and unions. Hospital organization's **Advanced Contract Tracing (ACT) Program** will continue to be critically important and will need to be revisited and refreshed. Polsinelli can provide further guidance as needed, but some workforce considerations include:

- ***Scope of Practice.*** Are there opportunities, within applicable licensing standards, to continue or expand the scope of practice of advanced practice providers to provide increased staffing flexibility to respond to the triple challenge the organization faces?

- ***Training.*** As the nation transitions to a new normal, is the organization prepared to provide clear communication to its workforce on the continued applicability of waivers of certain standards of care for certain populations if needed? Will there be unique needs that certain providers have because of new or expanded populations of patients, such as an increased need for mental health services? Will the organization need to provide new training to staff who are asked to work in new facility settings as it continue to isolate COVID-19 patients from others? Are there returning staff who will need to be trained on new modalities of care to minimize face-to-face patient interaction whenever possible? Does the hospital's Pandemic Response Plan include training considerations for training and redeployment of staff in the event of a surge?

- ***Ongoing Employee Needs.*** As the organization returns to a new normal, employees will continue to have unique needs as their communities re-open in stages, and in some instances, to an entirely new way of doing business. How the hospital manages this next phase of response to the ongoing pandemic will have important implications for relationships with organized labor and rankings as an employer of choice. What important learning lessons from the hospital's experience responding to the pandemic should be incorporated into its re-opening plan to support employees who will have ongoing childcare challenges, school-age children in virtual schools, caregiver roles, high-risk family members, transportation and general safety concerns and similar realities of life? Are there permanent modifications in the organization's employee assistance programs that should be implemented to support the ongoing and potentially increased stress hospital employees are facing both in the workplace and outside the workplace?

- ***Communication.*** Uncertainty and disruption to daily life and will continue and as patients return for treatment of non-emergent conditions and preventative care, hospital's employees will be on the front-lines to manage not only their responses, but the needs of likely anxious patients. Transparent and frequent communication will be critical. Has the hospital considered how to communicate to a broader group of staff regarding possible exposures from staff or patients that emerge as the ability to engage in contact tracing becomes robust and standardized? Is the hospital thinking about unique needs of different provider groups based on their patient population?

- ***Leadership.*** When does the hospital formally transition from crisis management/incident response/disaster recovery leadership structure to normal leadership structure if these are different? How do hospitals provide clarity to the workforce on leadership as it manages the triple threat? Is it supporting the additional needs of those leaders to protect against burn-out and more importantly support their ability to thrive and lead in challenging times?

- ***COVID-19 Testing.*** The COVID-19 status of the hospital's workforce creates a number of issues for consideration: Does the hospital have dedicated space available to accomplish routine screening of staff (which may include both symptomatic screening like temperature readings as well as collection of samples for clinical lab analysis)? Has the hospital developed procedures for the widespread and routine testing of staff, including policies to ensure required authorizations and consent, policies to protect the privacy of staff health data and policies to maintain compliance with federal anti-discrimination laws? Has the hospital considered potential policies to prioritize access to any future coronavirus vaccine or therapy, which may only be available in limited quantities?

Financial Considerations

Medicare Accelerated and Advanced Payments and Other Stimulus

As part of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), CMS expanded the existing eligibility of Medicare enrolled providers and suppliers to request and receive accelerated (providers enrolled under Medicare Part A, including hospitals) or advanced payments (suppliers enrolled under Medicare Part B, including physician practices) from the Medicare program. As of April 26, 2020, however, CMS suspended the advanced payments to Part B suppliers and announced that it is reevaluating all new and pending applications in light of direct grant fund payments made by the Department of Health and Human Services (HHS) under its Public Health and Social Services Emergency Fund. As of that date, CMS indicated it had paid out over $100 billion in accelerated and advanced payments, $59.6 billion of which went to Medicare Part A providers and $40.4 billion of which went to Medicare Part B suppliers.

While the program was still fully operational, Medicare Part B suppliers were able to request an advanced payment of up to 100% of the Medicare payment amount they had historically received over a 90-day period. Non-hospital Medicare Part A providers were (and as of this writing still are) similarly able to request accelerated payments for a 90-day period. Inpatient acute care hospitals, children's hospitals, and certain cancer hospitals could (and as of this writing still can) request accelerated payments for up to 100% of what they historically received over a 6-month period, while critical access hospitals can request up to 125% of their historic payment amount for up to a 6-month period. Funds received can be used for any purposes, and HHS did not bar providers or suppliers from applying to receive loans from the Small Business Administration (SBA) or receiving separate stimulus grant funds from HHS under the CARES Act Provider Relief Fund.

Any accelerated or advanced payments received under this program are loans and are subject to automatic recoupment by CMS or repayment by the provider or supplier. Because they are true loans, hospitals that have received either accelerated or advanced payments should start preparing now for the recoupment of the accelerated or advanced funds in order to prepare for the financial impact that such recoupments will have on their organizations. By way of reminder, the recoupment period begins 120 days after receipt of payment for all providers or suppliers that received an advanced or accelerated payments. Those receiving accelerated or advanced payments for 90-day windows will see 100% of any claims submitted during that 90-day period recouped (e.g., from days 121-210) while hospital providers receiving 6-months of accelerated payments may have a longer recoupment period (although there is currently some ambiguity in this position that we are working with CMS to resolve). For a small subset of Part A providers that receive Periodic Interim Payments (PIP Payments) the accelerated payment will be included in the reconciliation and settlement of their final cost report. In other words, for providers receiving PIP Payments, their PIP Payments will not be recouped, but any outpatient claims outside of the PIP Payment process would be subject to recoupment.

In both cases, hospitals experiencing a financial hardship can request that CMS recoup something less than 100% of all claims submitted during these periods, and such requests will be considered on a case-by-case basis. Any funds not recouped or otherwise fully repaid during these periods will result in the issuance of a demand letter for the outstanding balance of the advanced or accelerated funds from the Department of Treasury, and 30 days after the issuance of such demand letters will begin to accrue interest at a rate of 10.25%. Similar to the recoupment phase, hospitals experiencing financial hardships can request that CMS extend the repayment of any remaining funds into an extended payment plan and such requests will be considered on a case-by-case basis. Even providers receiving PIP Payments can request an extended repayment plan for any funds remaining to be repaid after the cost report reconciliation process is concluded. However, repayment in full is still required by PIP providers by the end of the repayment period (12 months after receipt of funds), even if the PIP provider's cost report settlement would occur beyond that period and interest at 10.25% will accrue to the PIP provider's outstanding repayment between the end of the repayment period and when their cost report is reconciled.

Select members of the Senate recently pressed CMS and the Department of Treasury to reduce or eliminate the 10.25% interest rate tacked onto any funds remaining

after the recoupment period and to allow more relaxed and favorable repayment terms. Whether such efforts will prove successful remains to be seen, but any provider or supplier receiving such funds should watch for any future developments with regards to recoupment and repayment of these funds.

Hospitals may also be eligible for assistance through Small Business Association loans or federal and state COVID-19 stimulus funding. The eligibility and terms of these programs are evolving and may change further due to additional expected government guidance, as well as future stimulus programs. Polsinelli will continue to provide updated information about these programs as they evolve, but hospitals should consult their legal and financial advisors to understand the terms of any other available options to obtain government funding.

Evaluation of Financial Position

Post-COVID-19 financial models may look very different from before the pandemic. Businesses rely on stable economic conditions in order to project their future performance, and the suspension of much economic activity during the COVID-19 crisis – and the time it may take for the economy to return to a normal productivity levels—makes it difficult for businesses to project their performance.

During the quarantine, while some businesses may have faced a patient surge, a number of facilities closed their doors or lost significant revenue from the loss of elective procedures. These are losses that are unlikely to be recovered. The stimulus programs are designed to help make up for these losses, but it is unclear whether they will be sufficient.

Many healthcare businesses will need to consider potential renegotiation of their obligations to lenders and bondholders. Federally-backed loans offer an automatic moratorium (Fannie, Freddie, and HUD provide for up to 90 days if requested), and while other lenders and bondholders are not subject to the same requirements, they may follow the federal government's lead in the midst of COVID. More importantly, lenders and bondholders typically understand that their interests are aligned with the success of the business, and forcing a liquidation is an outcome that yields the least recovery for everyone.

Tracking and modeling cash is critical; many healthcare businesses with excellent long-term prospects fail as the result of a cash crunch. Cash preservation can include staffing furloughs (be sure to consult HR and follow employment rules), minimizing variable expenses, and requesting extended payment terms with vendors and creditors. Consider seeking new or expanded lines of credit, drawing on available credit, or increasing capital contributions. Businesses that have taken a Medicare advance should model the future income trough that will occur as a result.

For some hospitals in financial distress, financial restructuring is likely to be required. Distress is always the art of exit strategies, and there are always six potential financial exits: (1) resurrection through top and bottom line fixes, (2) re-equitizing with new investor dollars (or grant dollars for non-profits), (3) refinancing, (4) re-amortizing the company's debts, (5) selling the business as a going concern, or (6) liquidating the business. Early intervention and planning helps significantly in achieving the better options.

Care for Uninsured and Medicare Bad Debt

Under the Families First Coronavirus Response Act (FFCRA) and the CARES Act, the federal government appropriated funds for claims reimbursement for healthcare providers testing and treating uninsured individuals with COVID-19-related diagnoses. Healthcare providers can submit COVID-related claims, starting with dates of service February 4, 2020, through a HRSA portal and be reimbursed for those claims generally at the Medicare rate. Further, state Medicaid agencies are able to seek waivers from the federal government in order to expand their Medicaid coverage of COVID-19 testing to a broader population.

Given these programs, there should be little increase in bad debt or uncompensated care related to COVID. Careful attention should be paid to ensure appropriate claims are filed within the 1 year timely filing limit. As hospitals considering expanding their service line offerings, we recommend ensuring that expenses related to uninsured patients are carefully reviewed to determine whether the patient had a COVID-related diagnosis, such that a claim can be submitted to HRSA for reimbursement, or whether the hospital should bill the patient according to its usual billing and collections, and financial assistance policies.

Payor Strategy

Many hospitals forced to fully or partially close during the COVID-19 pandemic experienced a drop in revenue and cash flow disruptions. As hospitals plan for reopening, ensuring prompt and full reimbursement, particularly from commercial payors, as operations return to pre-COVID-19 levels is critical. Careful and thorough preparation for reopening will include understanding and complying with payor guidelines while maximizing reimbursement and minimizing negative findings from retrospective payor audits. In addition, hospitals should still take care to comply with state and federal laws and regulations (e.g., state laws on scope of practice, federal laws addressing fraud and abuse).

The COVID-19 pandemic and subsequent legislation and rulemaking prompted payors to expand coverage for services related to COVID-19. Hospitals should review the scope of benefits offered by their most significant payors as these benefits may now be more generous. Most prominently, most payors are now required to cover testing for COVID-19. Other expanded opportunities for coverage include the expansion of telehealth benefits and lifting of prohibitions on mid-year benefit enhancements in connection with COVID-19 in the case of Medicare Advantage. Anecdotally, hospitals have also reported many other changes to the scope of benefits offered by payors.

New service models developed during COVID-19 such as telehealth capabilities, newly opened additional or non-traditional service sites, and other novel service models will need to be consistent with payor requirements on resuming service lines, both during the initial COVID-19 response period and on a more permanent basis. Any questions about coverage conditions or documentation expectations should be raised with payors prior to reopening. To the extent any new service models rely on federal or state waivers, a process should be put in place to monitor the waivers, as continued operations after a waiver expires or is withdrawn could impact reimbursement.

Hospitals should also confirm internally that their cash prices for COVID-19 testing and related services are posted online. Failure to do so may result in daily penalties. Lastly, because many patients have lost healthcare coverage during the COVID-19 pandemic after losing their jobs, hospitals may wish to explore additional patient assistance programs, such as discounting, or payment of COBRA premiums. These programs can raise compliance concerns depending on the facts and circumstances, so hospitals should consult with their compliance and legal departments before operationalizing any such program.

There may also be a window of opportunity for hospitals to address their relationships with payors due, in part, to the fact that they have experienced much lower utilization than usual during the COVID-19 pandemic. Hospitals should consider formal discussions with key payors to:

- Temporarily relax utilization management and administrative requirements, as encouraged by CMS and state insurance departments, to ensure that hospitals can focus their time and resources on care delivery. For example, hospitals anticipating continued COVID-19 burden after resuming non-emergent service lines could request that a payor remove the typical prior authorization requirement for inpatients or halt routine audits.
- Re-negotiate key matters such as long-term rates or any value-based or risk contracts that were negatively impacted by COVID-19. For example, quality of care metrics or stop-loss points could be re-negotiated.
- Resolve outstanding disputes to allow for short-term positive cash flow.

Some hospitals accepted advanced or accelerated payments from payors. These hospitals should review any associated repayment/reconciliation process upon reopening.

Key Payor Considerations: It is important to prepare revenue cycle, billing, and other key operational departments to ensure efficient reopening from a payor strategy perspective. Before reopening, hospitals should consider:

- Reaching out to referral sources and others regarding scheduling to ensure full schedule as soon as doors open. Hospitals should take care, however, not to discriminate between payors or offer illegal preferences to certain referral sources.
- Reviewing payor policies on elective procedures and COVID-19-related procedures for billing, coding, and documentation expectations.

- Offering billing and coding personnel refresher training on payor requirements for elective procedures and other procedures where payor policies might have changed due to COVID-19. If the billing and coding function is outsourced, hospitals should have advance conversations with the contractors regarding payor requirements and how to shorten claim submission timeframe.
- Communicating with the medical staff regarding documentation expectations, including expectations for prompt and accurate documentation.
- Reviewing and reinforcing documentation expectations and best-practices generally. Payor denials may be avoidable simply by following standard documentation practices.

Data Privacy and Security

As always, hospitals should consider state, federal, and international data privacy, security, and breach notification requirements for any information about employees. State law requirements apply to information collected about an employee depending on where s/he resides, not on where the hospital is located, and also depends on the type of information collected about the employee. The more information collected, the more risk to the employee and to the hospital employer—not only legal risk, but also cyber and other data privacy and security risks.

Further, federal law requirements, including HIPAA, also apply, including how hospitals can share information about their employees for employment purposes; how hospitals as employers can obtain information about employees from their own healthcare providers, and how hospital employers must implement information security controls for employee information. Hospitals and their employee health plans must be especially careful with regard to keeping patient information private and secure, and generally not using or sharing it for employment purposes without the consent/authorization of the employee.

Finally, while HHS has provided Notices regarding use of its enforcement discretion with regard to HIPAA requirements in certain specific, COVID-19 circumstances, HIPAA continues to apply, and the default for hospitals and their business associates should be compliance with all of the requirements of the HIPAA Privacy, Security, and Breach Notification Rules. As the PHE ceases, such Notices will be rescinded, so hospitals should not rely on such Notices for purposes of future data privacy and security efforts.

Communications and Marketing Plans for the Resumption of Non-Emergent Care

Developing a comprehensive communications and marketing plan around the hospital's resumption of non-emergent services is critical for ensuring that its physicians, practitioners, staff and patients understand: (1) that the hospital has resumed certain service lines; (2) which service lines are available in each facility operated by the hospital; and (3) that the hospital has a comprehensive program in place to ensure the safety of physicians, practitioners, patients and staff.

The following are key components for a communications and marketing plan:

- Develop a priority list of service lines to focus on based on factors such as clinical risks of further delay, effectiveness of alternative means of providing care (e.g., telehealth), and workforce availability;
- For the prioritized service lines, identify patients for immediate scheduling (e.g., those patients whose prior appointments were canceled due to the COVID-19 crisis and those patients who were in the process of being scheduled);
- Develop a script for rescheduling calls with patients based on the elements outlined below;
- Assign teams for scheduling calls and follow up;
- Reach out to local media for coverage of resumption of services;
- Identify key advertising media for publicizing reopening;

- Consider focusing on key elements of the hospital's role as a trusted healthcare provider in the community:
  - Use of patient testimonials;
  - Use of employee testimonials; and
  - Focus on the need to address all healthcare needs and not just COVID-19.

When crafting the hospital's message, consider including the following points:

- Health and wellness goes beyond fighting COVID-19;
- The hospital has a long history of serving all of the health needs of the community;
- The reopening is consistent with the governor's/state's executive order and federal guidance;
- Patients should feel safe because the hospital has implemented best practices to protect patients, their families and staff:
  - The hospital is following all applicable CDC and CMS guidelines;
  - Enhanced infection control and cleaning protocols are in place (consider including specific protocols that the facility has put in place to ensure safety);
  - All new patients and visitors (if permitted) are screened;
  - Highlight testing policies;
  - The hospital continues to coordinate its efforts with the local health department, as well as state and federal health officials.

Conclusions, Innovations and Opportunities

Given the magnitude of the COVID-19 crisis and its ongoing toll on all aspects of society, it is difficult to imagine that hospitals individually, and the healthcare industry as a whole, can emerge from this with more efficient and effective care delivery models. In very short order, however, hospitals, other healthcare providers, CMS, HRSA, FDA, state Medicaid programs, and private industries have found new models, new strategies, and new thinking about healthcare delivery. There is a lot to consider when developing plans for reopening facilities to non-emergency and non-COVID-19 care, but part of that consideration should be to step back and identify things that worked well, the hospital's learnings, and other potential hidden opportunities. Some things to consider include:

- ***Lines of Communication.*** The COVID-19 crisis demands increased communications across the industry. We have seen unprecedented collaboration and communication between facilities, suppliers and providers, facilities with patients and their families, facilities with their clinical and non-clinical staff, the healthcare industry and key government agencies, such as HHS, CMS, FDA to name a few. Consider what communication streams should remain open. What level of transparency with staff and the public should the hospital continue? What level of communication with governing agencies should the hospital advocate for? How can collaborative models between healthcare entities continue?

- ***Waivers.*** The country's COVID-19 response requires federal and state authorities to waive a significant number of regulatory requirements in order to ensure the safety of patients, staff, physicians and other practitioners. For example, healthcare delivery is transitioning from a fairly limited telehealth model to a significant array of services handled through telehealth regardless of where the patient and the practitioner are located. Site of service restrictions and licensure restrictions are waived. What works? What does not? What are the reasons to keep certain waivers in place while letting others lapse? What impact do those waivers have on patient experience and the quality of care? Now is the time to assess the success of any of the state or federal waivers and advocate for models of care that work and can continue to work post-COVID.

- ***Care Model Changes.*** As stated above, how hospitals care for patients of all types has changed during the COVID-19 PHE. Whether it is the shift to telehealth, increased use of home-based care, use of alternative venues of care, such as Hospitals without Walls, or others, hospitals should examine the effect of those care models and the impact on quality, patient experience, costs, reimbursement and staff. This may be a time to help redefine certain aspects of care delivery based on key learnings over a relatively short period of time and examining and sharing the hospital's experience may help drive that change.

- ***Going Back to "Normal."*** It is unlikely that there will be a time where the government can flip a switch and return the healthcare industry to how it existed prior to the declaration of the PHE, where all of the waivers are withdrawn and everything returns to "normal". Hospitals should plan, and advocate for, a staged or hybrid approach to ease the shift and to ensure there is time for all to consider the effectiveness and feasibility for some of the changes to stay in place. Further, hospitals should consider what plans and strategies it had in place prior to the COVID-19 crisis, and reassess whether the COVID-19 response changes any of those strategic plans.

- ***Supply Chain Diversification.*** Due to significant shortage of necessary supplies, hospitals must quickly learn to source supplies for other traditional and some non-traditional sources. Hospitals should consider whether that diversification should stay in place and to what extent. Some of that diversification may reduce costs while also increasing availability of products.

- ***New Business Opportunities***. During the COVID-19 crisis, did the hospital find any "gaps" that could be filled by considering new business opportunities?

Besides taking time to assess the hospital's response to COVID-19 and the changed healthcare world, we also encourage all hospitals to take stock of any potential compliance risk areas that may have been overlooked during the crisis or may be new because of the crisis. Some items to consider:

- ***Grants, Loans, Advanced Payments.*** Each of the stimulus and relief funds came out and were distributed quickly, often with evolving certification requirements. We have already seen examples of misuse of those funds, and it is clear that the government will take steps to audit the use of those funds. We encourage all healthcare providers to work with their compliance and financial teams to ensure its records related to those funds are clear and that the hospital is ready to face an audit related to its use and accounting of those funds.
- ***Waivers.*** Many federal and state waivers are set to expire at the conclusion of the PHE. To the extent they are not extended and implemented long-term, we recommend auditing areas impacted by waivers to ensure that each of those areas is back to operating in compliance with the prior rules. Areas of highlight would include, for example: physician relationships impacted by the Stark Law waivers, practitioner licensure for those practitioners not yet licensed or licensed in another state, site of services/venue waivers related to the use of non-hospital space for treatment of hospital patients.

Summary of Key Questions and Considerations for Hospitals

Based on the above guidance, hospitals should develop their plans for resuming non-emergent healthcare service lines based on a number of considerations, any of which Polsinelli can help hospitals evaluate. Some of those questions include:

- Has the state/region met the Gating Criteria to resume non-emergent healthcare service lines?
- Do state, county and applicable local guidance and emergency orders allow hospitals to resume providing non-emergent surgeries and other medical services and procedures? If so, do they impose additional or different requirements?
- What are the hospital's current levels of COVID-19 related resources, including intensive care unit beds, PPE, ventilators, and trained staff? What will the facility commit to keep on hand to prepare? Some states and municipalities may establish requirements for minimum supplies, space, or staffing.
- What was the clinical burden of any prior surge on the facility, such as overall admissions, inpatient census, intensive care unit census, emergency department throughput, burn rate of PPE, utilization of ventilators, and similar metrics?
- What protocols does the hospital need before providing non-emergent care to non-COVID-19 patients that are tailored to the ability of the hospital to safely restart care, the appropriate prioritization of service lines, and the ability to continue its COVID-19 surge readiness?
- What is the availability of PPE and other medical supplies and equipment? Can the hospital support resumption of certain services while maintaining stock for any additional COVID-19 surges? Has the hospital ensured its suppliers will be able to provide additional stock as needed, even if the COVID-19 crisis worsens? What is the hospital's contingency plan if supplies become limited?
- Has the hospital analyzed the potential clinical and resource burdens associated with the reintroduction of non-emergent and non-COVID-19 service lines?
- Has the hospital considered what policies and procedures are necessary regarding patient and staff testing?
- Has the hospital evaluated its ability to create non-COVID-19 care zones in the short- and long-term, along with the related space, separation, and infection control considerations? Has the facility considered other strategies, such as hospitals without walls, for cohorting and physically separating COVID-19 and non-COVID-19 patients?
- If the hospital was required to develop temporary practice locations or make alternative arrangements to care for the number of COVID-19 patients in an earlier surge, does it have ongoing arrangements to care for future patients?

- Does the hospital have a policies in place for continuing care through alternative means, such as telehealth, virtual check-in, and remote monitoring? Will anything within these policies need to change as service lines resume, particularly given federal and state encouragement to continue telehealth models to the extent it can be done safely?
- Has the hospital assessed its available workforce and considered workforce issues such as training, ongoing employee needs, necessary communications, leadership and testing?
- To the extent the hospital received Medicare Accelerated or Advanced Payments, is the hospital claims on appropriate uses of the various funds and is it prepared for any audits that may be done on the use of those funds?
- Has the hospital reassessed its financial position since the COVID-19 crisis and considered any strategic decisions in the face of financial distress?
- What waivers is the hospital currently operating under? Is someone designated to track waivers and to plan for the expiration of certain waivers?
- Has the hospital examined payor requirements related to service models developed during COVID-19 such as telehealth capabilities, newly opened additional or non-traditional service sites, and other novel service models?
- Has the hospital developed a communications and marketing plan with respect to the resumption of non-emergent in-person service lines in an effort to make its providers, staff and patients comfortable regarding the hospital's ability to keep all safe while resuming care?
- Has the hospital assessed its learnings in the wake of the initial waive of COVID-19 patients? What hidden opportunities exist and/or what should hospitals advocate for in order to ensure key learnings can be used in the delivery of healthcare services going forward?

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