Waive Your Waivers Goodbye: Planning for the End of COVID-19 Regulatory Flexibilities

Alabama Hospital Association 2021 Annual Meeting

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Emergency Declaration Timeline

- **Dec. 2019:** First case of COVID-19 discovered in Wuhan, China
- **Jan. 20, 2020:** First case in United States confirmed in Washington State
- **Jan. 30, 2020:** WHO declares global health emergency
- **Jan. 31, 2020:** HHS Secretary Azar declares public health emergency under Section 319 of the Public Health Service Act, effective as of Jan. 27, 2020
  - **Renewed:** Apr. 21, 2020, Jul. 23, 2020, October 2, 2020, and January 7, 2021
- **Mar. 13, 2020:**
  - President Trump declares nationwide emergency pursuant to Section 501(b) of the Stafford Act
  - Governor Ivey declares state public health emergency for Alabama under the Alabama Emergency Management Act of 1955
- **Mar. 17, 2020:**
  - HHS Secretary Azar makes PREP Act declaration
- **May 3, 2021:** Governor Ivey extends state public health emergency for Alabama and State Health Officer’s “Safer Apart” order; expiration dates set
  - “Safer Apart” Order: May 31, 2021
  - State Public Health Emergency: July 6, 2021
Waiver Authorities; Additional Flexibilities

- Social Security Act, Section 1135
- Telehealth Expansions – COVID-19 Relief Legislation
- Alabama COVID-19 Declarations
- Alabama Administrative Regulations
- PREP Act
- Alabama COVID-19 Immunity Protections
Social Security Act, Section 1135

• **Purpose**
  - Provide for sufficient health care items and services for Medicare, Medicaid, and CHIP enrollees
  - Allow reimbursement for health care providers that furnish items and services in good faith but are unable to comply with certain requirements waived under Section 1135(b)

• **Duration:** 60-day periods, not to exceed emergency, disaster, or public health emergency declaration

• **Tied to:**
  - Emergency or disaster declaration by the President under the National Emergencies Act or Stafford Act; or
  - Public health emergency declaration by the HHS Secretary under Section 319 of the Public Health Service Act
• **Waiver Authority:** Medicare, Medicaid, and CHIP requirements (including any regulation) pertaining to:
  • Conditions of participation or other certification requirements, program participation requirements, and pre-approval requirements
  • Requirements that physicians and other HCPs be licensed in the state in which they provide services if they have equivalent licensing in another state
  • EMTALA requirements related to: (i) transfer of an individual who has not been stabilized; and (ii) direction or relocation of an individual to receive an MSE at another location
  • Physician Self-Referral Law (Stark Law) Sanctions
  • Certain HIPAA Requirements (not a complete waiver)
Conditions of Participation

Hospital

- **Verbal Orders**: to be used “infrequently,” must be accepted by persons authorized to do so by hospital P&P, consistent with Federal and State law.
- **Patient Rights**: medical records, visitation, restraints and seclusion (typically limited to management of violent or self-destructive behavior).
  - Note that this waiver was tied to areas with “widespread outbreak” (51+ cases).
- **Reporting of Deaths Related to Restraints**: return to normal reporting requirements.
- **Medical Staff Approvals/Renewals**: no more leniency for late renewals or practicing without privileges.
- **Medical Records**: requirements for format and timely completion of medical records return.
- **Physical Environment**: life safety code and other stringent requirements for ensuring safety and wellness of patients return.

Tied to: Federal emergency declarations; cf state licensure requirements.
Conditions of Participation
CAH’s

Current Flexibilities
- **Personnel:** educational and certification requirements waived
- **Status/Location:** rural area and distance requirements waived to allow flexibility to establish surge site locations; Off-Campus/Co-Location Requirements waived
- **Beds/LOS:** CAH permitted to have more than 25 beds and greater than 96-hour average LOS
- **Physicians:** required to be available by direct radio/telephone/electronic communication but not required to be physically present

Return to Normal
- **Personnel:**
  - **CNS:** must hold master's/doctoral level degree in a defined clinical area of nursing
  - **NPs and PAs:** certifications and educational program requirements
- **Status/Location:** located in rural area/area treated as being rural; located at least 35 miles (15 miles for mountainous terrain/secondary roads) from any other hospital; Off-Campus/Co-Location Requirements
- **Beds/LOS:** limited to 25 beds and average 96-hour LOS
- **Physicians:** required to be present for medical direction, consultation, and supervision for the services provided;

Tied to: Federal emergency declarations
Requirements for LTC Facilities

Post-Acute Care

Current Flexibilities

- 3-day prior hospitalization requirement waived
- Level 1 PASARR screening may be performed post-admission, and patients should be referred for Level 2 screening ASAP
- CMS waiving some physical environment requirements to allow SNF care to be provided in non-SNF building (SNFs Without Walls)
- **Nurse Aide Training/Certs**: flexibility granted, but SNF still required to verify competency to provide nursing and nursing-related services
- **Physician/NPP Visits**: physician may delegate to other qualified practitioners, provided physician still supervises and delegation is consistent with state law and facility policies, and visits allowed to be provided via telehealth

Back to Normal

(42 C.F.R. Part 483)

- 3-day prior hospitalization required for coverage of a SNF stay
- PASARR screening required
- **Nurse Aide Training/Certs**: nurse aides cannot be employed longer than 4 months without nurse aide meeting training/cert requirements in §483.35(d)
- **Physician/NPP Visits**: required to be performed personally, in-person in many circumstances

Tied to: Federal emergency declarations
Conditions of Participation

Swing Beds

Return to Normal (42 C.F.R. § 482.58)

• Qualifying Hospital:
  • has fewer than 100 beds (some exclusions apply);
  • is located in a rural area;
  • does not have in effect a 24-hour nursing waiver under 42 C.F.R. § 482.58
  • has not had a swing bed approval terminated within the two years prior to the application for swing bed approval

• Hospital must provide skilled nursing facility (SNF) services substantially in compliance with SNF Requirements:
  • Resident rights
  • Admission, transfer, discharge rights
  • Freedom from abuse, neglect, exploitation
  • Social services
  • Discharge summary
  • Special rehab services
  • Dental services

• Admission subject to 3-day prior hospitalization requirement (just like SNF admissions)

Tied to: Federal and State emergency declarations
Conditions of Participation
Temporary Expansion Locations
(Alternate Care Sites)

- For the duration of PHE
- Waiver of physical environment requirements at 42 C.F.R. §§ 482.41; 485.623 and provider-based requirements at 42 C.F.R. § 413.65
- Allow hospitals to establish and operate as part of hospital any location meeting CoPs that continue to apply during the PHE
- Hospitals can change status of current provider-based department locations as necessary to meet needs of hospital and patients
- E.g., ASC enrolling as a hospital; hospital establishing new location
- Enrollment flexibility
  - Enrollment hotline
  - Waived application fees and criminal background checks
  - Waiver of site visits

Tied to: both Federal and State emergency declarations
The following COVID-19 billing/reimbursement flexibilities will be going away . . .

- **Use of Distinct Part Units**
  - Housing Acute Care Patients in the Inpatient Rehab Facility (IRF) or Inpatient Psychiatric Facility (IPF) Excluded Distinct Part Units
  - Care for Excluded IRF or IPF Patients in the Acute Care Unit of a Hospital
  - Flexibility for Inpatient Rehabilitation Facilities Regarding the “60 Percent Rule”
  - Waiver of Inpatient Rehabilitation Facility “3-Hour Rule”

- **Medical Necessity Issues**
  - Circumstances:
    - Private room for patients who need to be quarantined/isolated
    - Extended inpatient stay for patients who no longer need acute care, but need post-acute care, and there are not available post-acute care beds in the area
    - Medicare payment of DRG rate and any outlier costs for the entire stay until the patient is discharged

Tied to: Federal emergency declarations
EMTALA

Current Flexibilities
- Individuals (regardless of whether suspected for COVID-19) may be directed or relocated to another location to receive MSE
- An individual who has not been stabilized may be transferred to another facility if necessitated by the circumstances
- Alternate Testing Sites
  - not subject to EMTALA, even if run by hospital
  - Includes drive-thru testing sites
  - May be established collaboratively between providers, but each provider must have its own distinct space within the alternate testing site

Back to Normal (SSA § 1867, 42 C.F.R. § 489.24)
- If a patient “comes to the emergency department…”
- Medical Screening Examination (MSE)
  - And either . . . .
    - Stabilizing treatment; or
    - Appropriate transfer; or
    - Inpatient admission

Tied to: Federal emergency declarations; some state Licensure rules also in play
Stark Waivers

Current Flexibilities

- **Purposes:**
  - Diagnosis/medically necessary treatment of COVID-19
  - Securing services of physicians and other practitioners in response to COVID-19 outbreak
  - Ensuring ability of health care providers to address patient and community needs
  - Expanding capacity to address patient and community needs
  - Shifting diagnosis and care of patients to appropriate alternative settings
  - Addressing medical practice or business interruption to maintain availability of medical care and related services for patients and community

- **Waivers:**
  - Above/below FMV rental, lease, and other payments
  - Medical staff incidental benefits in excess of limits
  - Nonmonetary compensation in excess of limits
  - Certain loans between physicians and DHS entities
  - Expansion of physician-owned hospitals
  - Waiver of “same building” and “centralized building” requirements for group practices
  - Arrangements not meeting the writing requirement but otherwise complying with an exception

Tied to: Federal emergency declarations
HIPAA

• The following requirements under HIPAA are waived:
  • Requirement to obtain patient’s agreement to speak with family members or friends
  • Requirement to honor a patient’s request to opt out of the facility directory
  • Requirement to distribute notice of privacy practices
  • Patient’s right to request privacy restrictions and/or confidential communications under 45 C.F.R. § 164.522

• These items were not highlighted in the 1135 blanket waivers granted, but there were several enforcement discretion measures issued by OCR
Telehealth Expansions – COVID-19 Relief Legislation

• Several pieces of COVID-19 relief legislation added telehealth flexibilities to Section 1135 of the Social Security Act:

• Coronavirus Preparedness and Response Supplemental Appropriations Act
  • Waived originating site requirements (facility fee only available for previously eligible originating sites)
  • Allowed use of telephone, provided two-way audio-visual communications capable
  • Limited to “qualified providers” who had provided a service payable under Medicare to the patient within the last 3 years (or who is a member of a practice who met this requirement)
  • Limited to duration of COVID-19 public health emergency declaration by HHS Secretary (and renewals)

• Families First Coronavirus Response Act
  • Broadened “qualified provider” definition to include providers who provided a service to the individual that would be payable under Medicare if the individual were enrolled in Medicare

• CARES ACT
  • Waived all telehealth requirements under Section 1834(m) of the Social Security Act
  • Eliminated “qualified provider” requirements
  • Broadened waiver authority to apply in any declared emergency under Section 1135 instead of just the COVID-19 public health emergency
Telehealth

COVID-19 Flexibilities

• Services otherwise reimbursable under Medicare when provided in person
• Broader technology options available (real-time audio-visual, FaceTime, simple telephone call, etc.
• OCR statement of enforcement discretion for security of telehealth platform
• Urban or rural areas
• Services may be furnished in beneficiary home and any facility
• **Note:** does not apply where patient and remote practitioner are located in the same facility (these services are billed as in-person services)
• OIG offering flexibility to reduce or waive co-insurance
• CMS not auditing for prior relationship with patient
• DEA relaxed requirements for prior in-person visit before prescribing controlled substances via telehealth
• Additional services eligible to be provided via telehealth

Tied to: Federal emergency declarations

Back to Normal

• Only services otherwise reimbursable under Medicare when provided in person
• Real-time audio-visual communication technology required
• Secure platforms in compliance with HIPAA
• Patients located in rural areas, some expanded access for Medicare Advantage enrollees and dialysis and stroke patients
• Services furnished in limited subset of locations (hospitals, skilled nursing facilities, physician offices, etc.)
• Physicians, PAs, NPs, clinical psychologists, licensed social workers, etc.
• Pre-existing relationship with patient required
Alabama COVID-19 Declarations

- **Alabama Emergency Management Act of 1955**
  - Gives authority to the Governor of Alabama to declare a State of Emergency under certain circumstances (including Public Health Emergencies)
  - Authority to make, amend, and rescind the necessary orders, rules and regulations

- **Governor Ivey SOE Proclamations / Safer at Home Orders / Safer Apart Orders**
  - Alternative Standards of Care (original)
    - Serve as standard of care for purposes of Alabama Medical Liability Act
    - Tied to facility implementing its emergency operations plan
    - Health care professionals and assisting personnel deemed to be Emergency Management Workers
  - License extension for emergency services personnel for duration of declared emergency (expired 1/1/2021 according to 20th Supplemental SOE)
  - Licensure/Scope of Practice Rules (5th Supplemental SOE)
  - SHPDA Temporary CON; Expedited Pharmacy Permit (5th Supplemental SOE)
  - Liability Protections (8th Supplemental SOE)
  - Visitation Limitations; Elective Procedures (12th Supplemental SOE)
  - Mask Mandate (14th Supplemental SOE)
  - Mask Mandate removed eff. 4/9/2021 (26th Supplemental SOE)
  - Last Proclamation and Safer Apart Order (27th Supplemental SOE)
Alabama Administrative Regulations and Guidance

- Alabama Department of Public Health
- State Health Planning and Development Agency
- Alabama Board of Nursing
- Alabama Board of Medical Examiners
- Alabama Board of Pharmacy
- Alabama Medicaid Agency
Alabama Administrative Regulations and Guidance
Alabama Department of Public Health

- **Crisis Standards of Care**
  - “substantial change in usual healthcare operations and the level of care possible to deliver due to severe shortages of critical resources causing the delivery system to be overwhelmed”
  - Not specific to COVID-19, but updated during pandemic

- **Alternate Care Site Guidance**
  - Emergency approval for facilities to provide a different level of care than that allowed under the facility’s current licensure in response to surge situations and capacity issues
  - Limited to the duration of the public health emergency
  - If a provider desires to continue operating an ACS after the end of the public health emergency, must apply for licensure through normal channels

- **Waivers for Licensed/Certified Facilities**
  - Generally references CMS waivers issued on March 30, 2020, and updated throughout the pandemic

- **Inter-Facility Transfers and Discontinuation of Transmission-Based Protocols**
  - Guidance for care of COVID-19 patients in LTC facilities and hospitals
• 410-1-10-.05 and 410-2-5-.09
  • Emergency rules specifically related to COVID-19 State of Emergency were adopted in April 2020
  • Regular rules more broadly applicable to any State of Emergency finalized in November 2020
  • Application process and criteria for emergency waiver of CON requirements to address health needs during State of Emergency
  • **Duration of waiver:** until (i) discontinuation of services covered under waiver; or (ii) 60 days following termination of the declared State of Emergency
• **610-X-7-.13ER:** facilitates ADPH deployment of COVID-19 vaccines through the use of approved EMTs

• **610-X-4-.16ER:**
  • Existing rule provides for temporary nursing license during state SOE declared by Governor, alternate standards of care in licensed health care facilities, and other emergency response matters
  • clarification of exemption for gratuitous vaccine administration by nurses with retired or lapsed licenses; tied to state or national pandemic

• **610-X-4-.19ER:** relaxed requirements for reinstatement of lapsed license; tied to Governor’s COVID-19 SOE declaration

• **610-X-4-.14ER:** set fees for reinstatement of lapsed advanced practice approval for non-AL MSL RNs and non-Nursys verification of licenses; temporary emergency rule, subject to adoption of permanent rule
• BME
  • 540-X-3-.25ER: temporary emergency certificate of qualification to provide healthcare to acute care patients in licensed facilities who are suffering from or affected by COVID-19; certificates of qualification expire after 180 days, or the end of the Governor’s SOE declaration, whichever is sooner
  • 540-X-7-.71ER: expedite licensure process for anesthesiologist assistants to provide care to those suffering from/affected by COVID-19; rule expires after shorter of 120 days or end of COVID-19 state of emergency; 540-X-7-.72ER set supervision requirements
  • 540-X-7-.69ER: expedite licensure process for physician assistants to provide care to those suffering from/affected by COVID-19; 540-X-7-.70ER set supervision requirements

• MLC
  • 545-X-2-.08: allows physicians licensed in other states to obtain emergency medical license to provide care in Alabama; 120-day license periods tied to COVID-19 SOE declaration by Governor
  • 545-X-2-.09ER: physician whose license is inactive can apply for reinstatement for purpose of providing medical care to those suffering from/affected by COVID-19; temporary reinstatements expired as of 12/31/2020
• 680-X-2-.39.01ER: provides the standards for remote or off-site entry into permit holding pharmacies; tied to Governor’s COVID-19 SOE declaration

• 680-X-2-.26.01ER: authorizes emergency prescription refills under certain conditions; tied to Governor’s COVID-19 SOE declaration

• 680-X-2-.14.01ER: clarifies the duties of a licensed pharmacist and the role that technicians and other unlicensed individuals may fulfill; also extends the amount of time a technician has to complete required training; tied to Governor’s COVID-19 SOE declaration

• 680-X-2-.02ER: allows the Board of Pharmacy to grant temporary In-State Pharmacy Permits to applicants meeting certain requirements; permits issued under this rule expire 120 days after the effective date of this rule or at the end of the Governor’s SOE declaration, whichever comes first

• 680-X-2-.01ER: allows the Board of Pharmacy to issue temporary pharmacist practice permits to individuals who meet certain requirements; permits issued under this rule are valid for 120 days after the effective date of this rule or at the end of the Governor’s COVID-19 SOE declaration, whichever comes first.

• Joint Statement of Enforcement Discretion with BME: prescription of controlled substances via telehealth, etc. (consistent with DEA guidance); tied to state and national PHE
Alabama Administrative Regulations and Guidance
Alabama Medicaid Agency

- **560-X-6-.14ER and 560-X-6-.13ER**: allow medical providers to utilize telephone and telehealth consultations for Medicaid patients for the duration of the COVID-19 SOE declaration by Governor

- **560-X-1-.18ER**: This rule waives the need for patient signatures in instances where providers have discontinued the collection thereof due to health concerns so long as there is continued documentation of services provided; tied to Governor’s COVID-19 SOE declaration

- **560-X-13-.04ER**: waives requirements for EPSDT referrals for prior authorizations, face to face visits, or providing written prescriptions to Medicaid's fiscal agent; tied to Governor’s COVID-19 SOE declaration

- **560-X-11-.15ER**: EPSDT providers are not required to receive a referral for EPSDT services prior to rendering those services; tied to Governor’s COVID-19 SOE declaration

- **560-X-18-.04ER**: exempts emergency ambulance destinations with participating providers from restrictions on providing services; tied to Governor’s COVID-19 SOE declaration

- **560-X-18.03ER**: waives the requirement for prior authorization for providing nonemergency ambulance services to eligible Medicaid recipients; valid for 120 days or the duration of the COVID-19 State of Emergency.

- **560-X-1-.29ER**: Medicaid Agency Provider ALERTs will supersede the Administrative Code if there is a conflict between the two; tied to Governor’s COVID-19 SOE declaration

- **560-X-37-.10ER**: temporarily lifts the requirements of the ACHN DHCP referral process; tied to Governor’s COVID-19 SOE declaration
PREP Act

• provides immunity for **covered persons** with respect to **claims of loss** caused by, arising out of, or relating to the **administration/use** of **covered countermeasures** if a declaration has been issued by the HHS Secretary with respect to that countermeasure

• **in addition to** any immunity that may be provided under the Alabama Emergency Management Act of 1955, Governor Ivey’s State of Emergency Proclamations, or Act 2021-4

• tied to declaration of Public Health Emergency by HHS Secretary under 42 U.S.C. 247d-6d
Alabama COVID-19 Immunity Protections

- **Governor Ivey’s Eighth Supplemental SOE**
  - Provides liability protections for **businesses, health care providers, and other covered entities** engaged in **covered COVID-19 response activities** absent wanton, willful, reckless, or intentional misconduct
  - Also tied to reasonable attempts to comply with applicable public health guidance
  - By its nature, tied to Governor’s COVID-19 SOE declaration

- **Alabama Act 2021-4**
  - Largely patterned after the SOE immunity protections described above
  - Liability/immunity protections extend to December 31, 2021, or one year after the end of the declared health emergency with respect to COVID-19
Getting back to “normal” . . .

What does the end of the COVID-19 waivers and flexibilities look like?
### Getting back to “normal” . . .

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Getting back to “normal” . . .

What should you do?

• Review your CoPs, P&Ps, etc.

• Consult with your counsel, compliance officer, department heads, and others with subject-matter expertise on regulatory requirements

• Make preparations to “flip the switch” where necessary, or to phase back to normal where longer lead time is available

• Make sure your files clearly document the waivers/flexibilities implemented, reasons for implementation, and when things are returned to normal

• Be prepared for audits of the waivers/flexibilities used
Questions?

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