Morgan Lewis

COVID-19 HEALTHCARE PROVIDER UPDATES

MEDICARE WAIVERS

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Agenda

- Telehealth
- Section 1135 Waivers
- Individual Waivers and EMTALA
- 1135 Waiver and Stark Law

TELEHEALTH

The Rise of Telehealth?

- Telehealth has been a growing medium in the healthcare industry for nearly a decade
  - When deployed effectively, it can reduce cost, increase access, and enhance quality for the services it is designed to support
  - The development of sophisticated smart phone technology with video capability has been a substantial boost for telehealth
    - Entirely different medium than "internet questionnaires"
    - Adoption in many states and by many commercial insurers
- However, despite these gains, telehealth has not been widely accepted in the Medicare program

The Impact of COVID-19

- The infectiousness of COVID-19 has forced us to practice social distancing or risk catching and spreading the virus

- Given this new reality, telehealth has been tapped as the solution

- The current state of laws around telehealth, including reimbursement and licensure, prevent the type of widespread and immediate adoption many state and federal officials are looking for to address the growing crisis
  - Limitations on patient use, limitations on reimbursement, and limitations on who can provide

Recent Actions Surrounding Telehealth

- On March 6, Congress passed its first COVID-19 related bill
  - Coronavirus Preparedness and Response Supplemental Appropriations Act (CPRSAA)
- This law temporarily sets aside the two main barriers to telehealth in the traditional Medicare program
  - Geographic area
  - Originating site
- Under the law, only applies to established Medicare patients of a qualified supplier
  - However, in program instructions, CMS indicated it is exercising enforcement discretion and will not audit for whether the patient is new or established to the supplier

Recent Actions Surrounding Telehealth

- In that same CMS program instruction, as well as in guidance from OCR and OIG issued that same day (March 17), the federal government was aligned in providing regulatory relief to telehealth providers to get them seeing patients as fast as possible

  - OIG announced that it is exercising enforcement discretion for copay waivers for covered telehealth services

  - Services do not need to be for the purpose of diagnosing or treating COVID-19

Recent Actions Surrounding Telehealth

- On March 15, with a retroactive effect date to March 1, HHS also issued a licensure waiver
  - This waiver allows Medicare/Medicaid payment for services even if a supplier is not licensed in the state in which the services are provided
  - However, this does not mean that physicians can practice in any state so long as licensed in one state – state law still applies
- Several states have waived their licensure requirements to allow out-of-state licensed physicians to provide telehealth on a temporary basis
  - Not all states have done this and there are nuances to each state's waiver

SECTION 1135 WAIVERS

Legal Authority for Section 1135 Waiver

- The President's March 13, 2020 Declaration of Emergency under the National Emergencies Act triggered the operation of HHS's "Authority to Waive Requirements During National Emergencies"
  - Section 1135(g)(1)(A) of the Social Security Act (42 U.S.C. § 1320b-5)
- Alex Azar II, Secretary of HHS, in turn, issued a "Waiver or Modifications of Requirements Under Section 1135 of the Social Security Act"
  - https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx
  - Issued March 13, 2020 *with retroactive effect to March 1, 2020*

The Secretary's 1135 Waiver

- HHS waives or modifies multiple requirements of the Medicare, Medicaid, and Children's Health Programs "*but in each case,* ***only to the extent necessary, as determined by [CMS]*** *to ensure that sufficient health care items and services are available…*"
- Effectively lifts statutory and regulatory requirement for individuals/providers furnishing services to program beneficiaries
  - Permits reimbursement (absent any determination of fraud and abuse) for services furnished during the emergency period despite not meeting certain program requirements

The Secretary's 1135 Waiver *cont.*

- Waiver may apply to:
  - Certain conditions of participation, or certification requirements for providers and pre-approval
  - Requirements for licenses by providers in the state in which they are providing emergency services
  - EMTALA sanctions for direction or relocation of a patient pursuant to a state emergency preparedness plan
  - Sanctions under the Stark Law
  - Limitations on payments under Medicare Advantage plans relating to out of network services
  - Penalties under certain elements of HIPAA
  - Deadlines and timetables for performance of required activities (modification not waiver)

Concept of Blanket Waivers

- CMS has made a broad determination under its authority that a statutory/regulatory requirement is lifted for all affected providers/individuals
  - "When a blanket waiver's issued, ***providers don't have to apply for an individual waiver***. Blanket waivers prevent access to care gaps for beneficiaries affected by the emergency."
    - https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Resources/Waivers-and-flexibilities

COVID-19 Blanket Waivers

- CMS Issued "COVID-19 Emergency Declaration Health Care Providers Fact Sheet"
  - https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf
  - Specific categories of relief include:
    - Flexibilities on acute bed expansion (e.g. CAH limits lifted, housing acute patients in excluded units and visa versa)
    - Flexibilities on DME waiver of replacement requirements (i.e. face-to-face encounter, new physician order, etc.)
    - LTCH stay requirements
    - HHA OASIS timeframes for transmission
    - Licensed providers from out of state may provide services in another state (Medicare & Medicaid only)
    - Expedited processes for provider enrollment
    - Certain appeals processes in fee for service, MA and Part D
  - Blanket Waiver also applies to three day inpatient stay requirement for SNF coverage
    - CMS Administrator issued separate "Finding" Supporting removal of this requirement on March 13, 2020

COVID-19 1135 Waivers for States

- State specific waivers issued by CMS for Florida and Washington
- Additional states expected to be added; CMS posts to website below:
  - https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/federal-disaster-resources/index.html
- Statewide waivers provide program flexibilities beyond the "blanket waiver" based on the requests of state health agencies
- March 23, 2020 – 11 more states granted Section 1135 waivers

INDIVIDUAL WAIVERS

Individual Waivers

- Individual Waivers are those that are specific to an individual provider or to an individual State
- As mentioned earlier, these can reflect specific needs of specific facilities that cover a broad range of areas, including: (a) CoPs; (b) EMTALA; (c) Stark; (d) HIPAA; and (e) performance deadlines
- EMTALA and Stark will be addressed shortly
- State requirements are separate and sometimes waivers on the identical requirement are required at both levels, such as licensure

Individual Waivers (cont.)

- Individual waivers can be submitted by drafting a correspondence to the applicable CMS office
- The correspondence should include "justification" for why the waiver is necessary
- The most successful waiver requests will be those that are:
  - Narrowly tailored to the crisis at hand, both in time and scope
  - Supported by an adequate description of the facts and circumstances that lead to the need for the waiver
  - Reflect that other remedial measures have already been taken or considered and have been deemed inadequate

Individual Waivers *(cont.)*

- It is important to distinguish those circumstances where a waiver is necessary and where it is not
- It is not necessary to seek a waiver to exceed 25 beds if a facility is a CAH
- It *is* necessary to seek a waiver if the facility is an IRF and will be taking in acute care patients that threaten the IRF's 60% rule compliance
- It is then also necessary to make sure that any State relief also be sought
  - In some cases, the State may need to seek its own waiver (13 states have waivers as of today's date)
  - In other cases, the State may be able to waive on its own
  - An example: CMS has issued blanket waiver authority regarding out of state licensure; it still may be necessary for the State to issue its own matching waiver, which may require seeking CMS's waiver

Individual Waivers *(cont.)*

- CMS has stated specifically that waivers can be sought by States for the following:
- Prior authorization requirements
- Providing care to out of state Medicaid beneficiaries
- Suspension of enrollment requirements
- Suspension of in-state licensure requirements
- Suspension of screening requirements for SNF residents

Individual Waivers *(cont.)*

- CMS lists the following addresses for seeking individual waivers
- ROATLHSQ@cms.hhs.gov (Atlanta RO): Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee
- RODALDSC@cms.hhs.gov (Dallas RO): Arkansas, Louisiana, New Mexico, Oklahoma, Texas
- ROPHIDSC@cms.hhs.gov (Northeast Consortium): Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia, New York, New Jersey, Puerto Rico, Virgin Islands, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
- ROCHISC@cms.hhs.gov (Midwest Consortium): Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin, Iowa, Kansas, Missouri, Nebraska
- ROSFOSO@cms.hhs.gov (Western Consortium): Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming, Alaska, Idaho, Oregon, Washington, Arizona, California, Hawaii, Nevada, Pacific Territories.

1135 Waiver: Emergency Treatment and Labor Act (EMTALA)

- EMTALA Waiver Language :
  - Sanctions under section 1867 of EMTALA for the direction or relocation of an individual to another location to receive medical screening pursuant to an appropriate state emergency preparedness plan or for the transfer of an individual who has not been stabilized if the transfer is necessitated by the circumstances of the declared Federal public health emergency for the COVID-19 pandemic.
- Limited scope of the waiver; relief from potential civil monetary penalties and from exclusion from federal healthcare programs
- Conditions that must be met to apply the waiver
- Duration of the waiver
- Case-by-case waiver request

1135 Waiver: Emergency Treatment and Labor Act (EMTALA)

- On March 9, the CMS Quality, Safety and Oversight Group issued a guidance memo titled "Emergency Medical Treatment and Labor Act (EMTALA) Requirements and Implications related to Coronavirus Disease 2019 (COVID-19)"
  - https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and/emergency-medical-treatment-and-labor-act-emtala-requirements-and-implications-related-coronavirus
- CMS's EMTALA Memo addresses options for alternative screening sites, obligations when screening possible COVID-19 cases and transfer/recipient hospital obligations
- Includes Fact Sheet and Q&A Document Attachments
- Even under a waiver, hospitals must continue to work to meet non-waived EMTALA obligations

1135 Waiver: Stark Law

- Included in the Secretary's March 13 1135 Waivers was the following: "Sanctions from section 1877(g) (relating to limitations on physician referrals) under such conditions and in such circumstances as the Center for Medicare & Medicaid Services determines appropriate."
- The challenges created by strict liability nature of the Stark Law are exacerbated by the COVID-19 public health crisis.
- As hospitals and other healthcare providers respond to the crisis, they will inevitably engage physicians for assistance and likely establish "compensation arrangements" as defined by the Stark Law. Most compensation arrangement exceptions include the "writing" requirement.
- Other providers may seek to support certain groups of physicians that are harmed as a result of the crisis, such as the cancelation of elective surgeries.

1135 Waiver: Stark Law

- The Stark Law waiver is not self-implementing.
- Request for waivers related to COVID-19 will be handled by CMS' central office in Baltimore. Requests can be sent to 1877CallCenter@CMS.hhs.gov. Include the words "Request for 1877(g) Waiver" in the subject line of the email.
- All requests should include the following information:
  - Name and address of requesting entity
  - Name, phone number and email address of a designated representative
  - CMS Certification Number or Taxpayer Identification Number
  - Nature of the request
- CMS will grant waivers only on request and on a case-by-case basis, based on the details concerning the actual or proposed financial relationship between the referring physician and entity.
- Unless and until a waiver is granted to the requesting parties, compliance with the Stark Law is required.

1135 Waiver: Stark Law

- Most potential compensation arrangements with physicians can meet an existing Stark Law exception:
  - Employment
  - Fair Market Value
  - Personal Service Arrangements
- Do whatever you can to memorialize the arrangement in writing (e.g., emails) and includes the essential terms. Signatures can be obtained 90 days from the date on which the arrangement became noncompliant. 42 CFR §411.353(g)
- Physicians may donate their time to tax exempt entities so long as the donation is not solicited or offered in a manner that takes into account the volume or value of referrals between the parties. 42 CFR §411.357(j)

Biography

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Gregory N. Etzel concentrates his practice on the representation of hospitals and other healthcare providers in a variety of complex legal transactions and regulatory litigation. Prior to joining Morgan Lewis, Greg spent four and a half years in-house as the vice president of legal affairs at The University of Texas Medical Branch (UTMB), providing legal counsel and representing the entire institution on a wide range of issues involving strategic initiatives, hospital and medical school operations, transactions, litigation management, public information, and international affairs.

Biography

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Andrew Ruskin counsels hospitals, pharmaceutical and medical device companies, and Medicare Advantage plans, among others, on a range of Medicare and Medicaid regulatory, litigation, and transactional matters. Andy advises on strategic issues surrounding coverage, reimbursement, and compliance, as well as drug pricing and price reporting. He defends clients in investigations by the US Attorney's Office and the Department of Health and Human Services Office of Inspector General, and he appears before several regulatory tribunals, such as the Provider Reimbursement Review Board and the HCPCS Committee.

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Albert W. Shay focuses his practice on counseling healthcare companies of all types on regulatory, fraud and abuse, Stark law, Medicare reimbursement, and transactional matters. Al devotes a substantial portion of his practice to corporate compliance issues, including internal and government investigations, and has experience representing clients before regulatory agencies such as the Centers for Medicare and Medicaid Services (CMS), the US Department of Health and Human Services' Office of Inspector General, and the Provider Reimbursement Review Board.

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Lauren Z Groebe focuses her practice on regulatory and transactional matters affecting clients in the healthcare sector. She counsels hospitals, health systems, hospices, pharmacies, and private equity clients, among others, across a range of regulatory issues, including matters related to compliance with HIPAA, the 340B Program, the Sunshine Act, fraud and abuse laws, Medicare and Medicaid enrollment, and licensure requirements. Lauren also advises clients on the corporate and healthcare regulatory aspects of merger and acquisition transaction

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Jacob Harper advises stakeholders across the healthcare industry, including hospitals, health systems, large physician group practices, practice management companies, hospices, chain pharmacies, manufacturers, and private equity clients, on an array of healthcare regulatory, transactional, and litigation matters. His practice focuses on compliance, fraud and abuse, and reimbursement matters, self-disclosures to and negotiations with OIG and CMS, internal investigations, provider mergers and acquisitions, and appeals before the PRRB, OMHA, and the Medicare Appeals Council.

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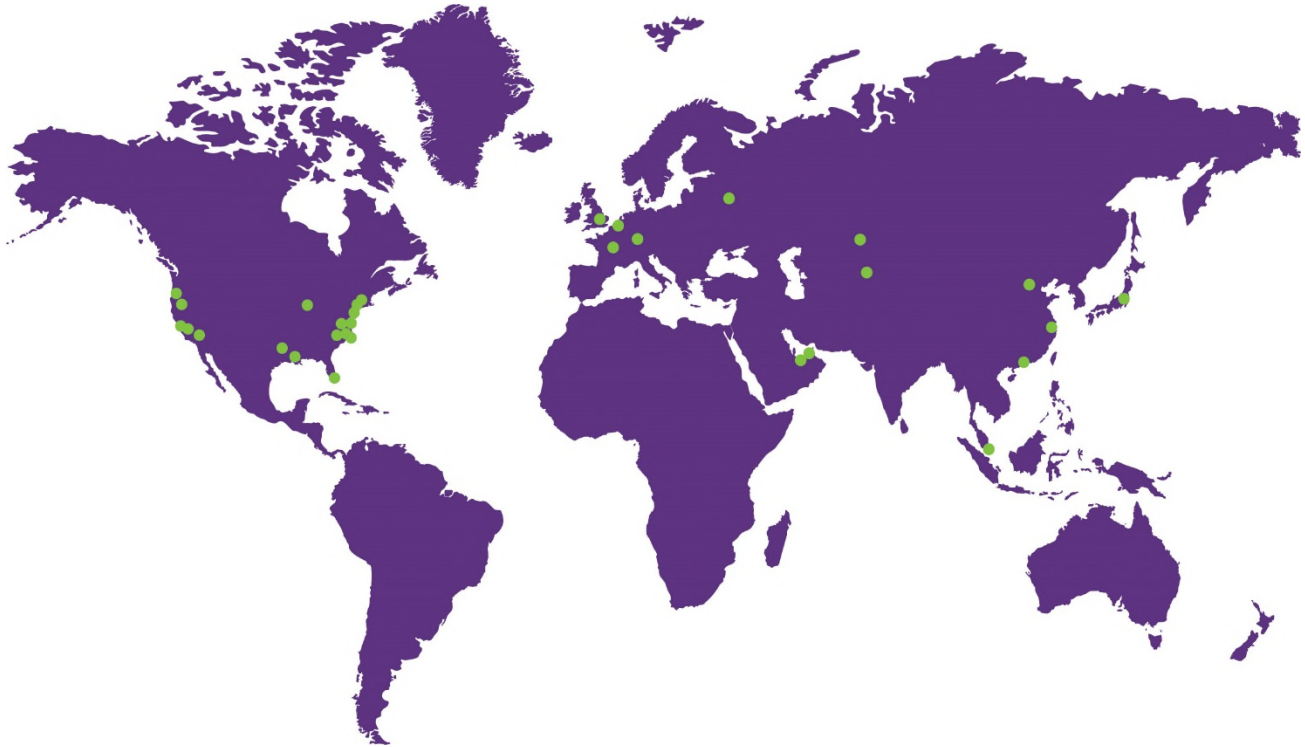

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