The 21st Century Cures Act: The Impact on Providers and How Providers Can Respond

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Hosted by Mediware & Frier Levitt

- Mediware
  - Over 150 experienced software and homecare industry professionals in the areas; HME, Home Infusion, Specialty Pharmacy, and Home Health Agency

- Frier Levitt
  - Frier Levitt is a national boutique healthcare law firm, providing comprehensive regulatory, transactional and litigation advice to the healthcare industry with a keen focus on representing pharmacy clients.
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Polling Question #1:

How do you anticipate the 21st Century Cures Act will affect your company/services?

1. Very Positively
2. Mostly Positively
3. Neutral
4. Mostly Negatively
5. Very Negatively
WHAT IS THE 21ST CENTURY CURES ACT?

- On Dec. 13, 2016, President Obama signed the 21st Century Cures Act

- Received bipartisan support, with 170 Republicans and 174 Democrats voting in favor of the bill.

- Reforms standards and appropriations for biomedical research, provide $1.75 billion annually for the National Institutes of Health (NIH) and $110 million for the Food and Drug Administration (FDA).

- Contains various provisions that directly affect healthcare providers’ reimbursement.
WHAT IS THE 21ST CENTURY CURES ACT?

- The Act changes the reimbursement methodology for infusion drugs and biologics furnished through DME

- Revises Section 603 of the Bipartisan Budget Act of 2015 (“Section 603”) and provides exception for off-campus provider-based departments (“PBDs”)

- Act impacts off-campus provider-based hospital outpatient departments that do not qualify for exemptions at the time Bipartisan Budget Act of 2015 was passed on Nov. 2, 2015

- The grandfather date was extended for HOPD facilities to qualify for payment under the outpatient prospective payment system, rather than at the lower “site-neutral” rate
HOW DOES THE 21ST CENTURY CURES ACT EFFECT HOME INFUSION?
Reimbursement Rate for Infusion Drugs

- Sec. 5004 of the Act reduces overpayments of infusion drugs
- An OIG report concluded that Medicare had overpaid for infusion drugs
- OIG states the new pricing methodology will better reflect actual transaction prices
- Infused drugs and those administered intravenously, intramuscularly or subcutaneously, are typically paid under the Medicare Part B fee schedule
- Effective January 1, 2017, the payment amount for Part B infusion drugs and biologics furnished through DME will be the Average Sales Price (ASP) plus 6%, rather than the historical payment amount based on 95% of the manufacturers’ Average Wholesale Price (AWP).
Home Infusion Therapy: 4-year Delay

- Act creates a new payment system for certain home infusion therapy services paid under Medicare Part B in 2021
- Sec. 5012 of the Act updates the payment policy for home infusion therapy
- It implements a single payment for certain items and services furnished by qualified home infusion therapy supplier
  - (a) professional and nursing services;
  - (b) training and education (not otherwise paid for as DMEPOS);
  - (c) remote monitoring; and
  - (d) monitoring services for providing home infusion therapy and drugs
Home Infusion Therapy: 4-year Delay

- The single payment unit is for each infusion drug administration calendar day in the patient’s home BUT such payment cannot exceed payment for infusion therapy services furnished in a physician office setting.

- Home infusion therapy suppliers (i.e., a pharmacy, physician or other licensed provider or supplier) will need accreditation and meet standards of care established by Medicare Advantage plans for home infusion therapy.
New Payment Rules for Hospital Off-Campus Provider-Based Departments (HOPD)

- Section 603 of the Bipartisan Budget Act of 2015 barred CMS from continuing to pay hospitals the OPPS rates for services furnished in OPBDs beginning January 1, 2017.
- New payment rules do not apply in several situations.
New Payment Rules for Hospital Off-Campus Provider-Based Departments (HOPD)

- Excepted items and services that will receive OPPS and not the lower site-neutral rate after January 1, 2017:
  - By an off-campus dedicated emergency departments;
  - By an off-campus HOPD (located farther than 250 yards from a hospital's main campus) that was billing for covered outpatient provider department (OPD) services furnished prior to November 2, 2015, (i.e., the date of enactment of section 603 of the Bipartisan Budget Act of 2015 (Section 603)) that has not impermissibly relocated or changed ownership;
  - In a PBD that is “on the campus,” or within 250 yards, of the hospital or a remote location of the hospital
New Payment Rules for Hospital Off-Campus Provider-Based Departments (HOPD)

- Beginning January 1, 2017, services at non-excepted locations will be paid based on a reduced payment amount that is generally equal to 50 percent of the OPPS rate.

- Non-excepted items and services Medicare Physician Fee Schedule ("MPFS") or ambulatory surgery center reimbursement rates.

- Any facility not located on that main campus (generally within 250 yards) is considered “off-campus” and must satisfy the provider-based rules in order to be treated by the main hospital as provider-based.
Grandfathered Off-Campus HOPDs

- Extended the grandfather date for facilities to qualify for payment under the outpatient prospective payment system ("OPPS"), instead of lower Medicare Physician Fee Schedule.

- OPBDs that furnished OPBD services prior to November 2, 2015, so long as they are billed under the OPPS in accordance with timely filing limits,
  - Services did not have to be billed by November 2, 2015.

- Hospital Medicare Administrative Contractor must have received attestation and certification documents by Feb. 13, 2017 in order to be grandfathered in 2018.

- Use of new modifier for HOPDs will be grandfathered in 2018 not 2017.

- CMS guidance states a “grandfathered” off-campus HOPD may expand its footprint so long as it retains the same physical address that is listed on the Medicare 855A enrollment record as of November 2, 2015.
  - HOPD may expand existing physical space and continue to bill under the OPPS.
Grandfathered Off-Campus HOPDs

- Takeaway - an excepted HOPD will receive payments under OPPS for all billed items and services, regardless of whether it furnished them prior to the enactment of Section 603, as long as the OPBD remains excepted, i.e., meets the relocation and change of ownership requirements.

- Key factor is the physical address for the off-campus HOPD is not altered and continues to match the address reported on the Medicare 855A enrollment record as of November 2, 2015
Excepted OPBD that undergoes a change of ownership will remain excepted only if

- the ownership of the main provider is also transferred and,
- the Medicare provider agreement is accepted by the new owner

**Takeaway** - sale of grandfathered HOPD alone will result in the loss of the excepted status.

**Service line expansions**

- CMS declined to limit excepted off-campus PBDs to include only those items and services within the so-called “clinical family” of items and services that were furnished and billed as of November 2, 2015 in its final rule
Do you have an HOPD?

Criteria:

- “Department of a provider” includes both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility.
- It generally must be located within a 35-mile radius of the campus of the main hospital.
- Its financial operations must be fully integrated within those of the main provider.
- Its clinical services must be integrated with those of the main hospital (for example, the professional staff at the off-campus outpatient department must have clinical privileges at the main hospital, the off-campus outpatient department medical records must be integrated into a unified retrieval system (or cross reference) of the main hospital), and patients treated at the off-campus outpatient department who require further care must have full access to all services of the main hospital.
- It is held out to the public as part of the main hospital.
- A hospital is not allowed to have more than one single “main” campus for each hospital.
Partial Relief for “Mid-Build” HOPDs

- In final regulation, CMS stated the law did not provide for an exception for mid-build off-campus PBDs and, therefore, CMS could not grandfather them.

- Partial relief for mid-build off-campus PBDs, permitting them to be paid under OPPS if they qualify for relief by meeting certain requirements:
  - The hospital must have had a binding, written agreement with an outside, unrelated party for the actual construction of the off-campus PBD on November 2, 2015.
Partial Relief for “Mid-Build” HOPDs

- Each off-campus PBD must submit both:
  - a certification from the hospital’s Chief Executive Officer or Chief Operating Officer that the off-campus PBD meets the “mid-build” definition, and
  - a provider-based attestation in accordance with 42 C.F.R. Sec. 413.65 within 60 days of the enactment of the Act. — The hospital must include the PBD as part of the hospital on its 855A enrollment form.

- Hospitals that meet the applicable requirements for the partial relief for “mid-build” projects will still be paid on a site-neutral basis during 2017, but they will be able to receive payments under OPPS beginning January 1, 2018.
Relocations

- Relocating an excepted off-campus PBD will remove its excepted status
- CMS concerned that hospitals would be able to relocate excepted off-campus PBDs to larger facilities, purchase additional physician practices, and move these practices into the larger relocated facilities that would continue to be paid under the OPPS
- Section 603 applies to off-campus PBDs as they existed at the time the law was enacted
- Will be considered "new" if HOPD "moves or relocates from the physical address that was listed on the provider’s hospital enrollment form as of November 1 2015."
- BUT exceptions will apply for circumstances outside a hospital’s control, such as natural disasters, significant seismic building code requirements or significant public health and public safety issues
- Relocation requests are reviewed by CMS on a case-by-case basis.
- Takeaway – An on-campus PBD that was billing under the OPPS prior to November 2, 2015 would not maintain excepted status if the PBD moved off-campus after the date of enactment of the Act
Starting June 2017, Medicare Administrative Contractors (MACs) will be required to publish a summary of evidence it considered when developing an LCD.

An LCD is a coverage determination by a MAC on whether a particular service or item is reasonable and necessary under Medicare within that MAC’s geographical jurisdiction.

Under the Act, at least 45 days before a new or revised LCD is effective, MACs are required to publish on their website:

- The LCD
- Links to the proposed LCD and a response to comments submitted to the MAC concerning the LCD;
- Where and when the proposed LCD was first made public;
- A summary of the evidence that the MAC considered in developing the LCD, including a list of sources
- An explanation of the rationale that supports the MAC’s determination
Changes will improve the LCD procedural process

Increased transparency will allow industry stakeholders to have access to the evidence the MAC considered when developing or revising the LCD

Stakeholders may also provide additional information for MAC to consider or reference.
The Act requires the Secretary to study by January 12, 2017, the effect of applicable payment adjustments on the number of DMEPOS suppliers that ceased to conduct business in 2016, and the availability of DMEPOS to Medicare beneficiaries in 2016.
Polling Question #2:

Based on your knowledge of the Act, how do you feel the Act will impact patient access to care?

1. Significantly limit access
2. Limit access
3. No affect on access
4. Increase access
5. Significantly increase access
WILL CHANGE IN REIMBURSEMENT CAUSES PARADIGM SHIFT?

Home Infusion

Facility Based Infusion

Change in Reimbursement Will Likely Cause Infusion Therapy to Shift Back to Facilities and Physician Offices
HEALTHCARE CORPORATE PLANNING SOLUTION TO 21ST CENTURY CURES CHANGE IN REIMBURSEMENT?

- Collaboration Among Providers
- Leverage Home Infusion Providers’ Expertise
- Joint Venture Between Home Infusion Providers and Physicians, and/or Facilities
- Management Services Arrangement ("MSA")
- Risk-Based Contracts
- Episode of Care
Advocacy

- Provider Organizations
- Political solutions
- Special interest/patient advocacy groups
Polling Question #3:

CareTend: Business management software system for home infusion, specialty pharmacy, and HME

- Complete revenue cycle management tools
  - Send clean claims the first time
  - Track DSO, write offs, old AR, adjustments
  - Real-time reporting allows you to track denials, and conduct detailed financial analysis within seconds
Questions?
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