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CMS IMPLEMENTATION OF SECTION 603 OF THE BIPARTISAN BUDGET ACT: IMPLICATIONS FOR PROVIDER-BASED CLINICS

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Agenda

- History of provider-based status
- Section 603 of the Bipartisan Budget Act
- Services in dedicated emergency departments
- Main and ancillary campuses
- Relocations
- Service lines
- CHOWs
- Evidence of grandfathered status
- Changes of ownership
- Billing for non-excepted services in 2017

History of Provider-Based Status

- Provider-based status has been part of the Medicare program since its inception
- Requirements initially very relaxed because of the limited payment implications
- After implementation of IPPS, concerns with increased value of physician clinics converted to provider-based status
- Series of Program Memoranda issued in 1990s
- Provider-Based Rule finalized in 2000
- MedPAC report in 2012 identifies that there is little value to furnishing E/M services in hospital-based space, and that Medicare could save $5 billion over 5 years by equalizing payment across settings
- BiBA enacted on November 2, 2015 and is estimated at saving $9.3 billion over 10 years

BiBA 2015

- Creates distinction between off-campus outpatient departments of a provider that began billing after November 2, 2015 and:
  - Off-campus PBDs that began billing before that date
  - On-campus outpatient departments
  - Dedicated emergency departments
- For the former category, provider-based billing is only available through December 31, 2016
  - Thereafter, payment is made under the otherwise applicable payment system

DEDs

- Terms comes from EMTALA regulations and includes an entity that meets one of the following:
  – Licensed by State as an ED
  – Held out to the public as a place where care can be furnished on an urgent basis without an appointment
  – 1/3 of all visits are on an urgent basis
- CMS proposes exempting <u>all</u> services furnished in a DED
  – Relocation and service line addition prohibitions do not apply
  – Unclear if would remain exempt if some services are completely unrelated to the care of urgent care patients
  – Would it be possible to add ED services to a site that was already under development and have it be exempt?

Qualifying as On Campus

- No change to definition in 42 C.F.R. § 413.65
  - Can either be within 250 yards of the main buildings; or
  - Other sites determined on a case-by-case basis by the CMS ROs
- For remote locations (ancillary campuses), the test is 250 yards (straight line) from "any point" of a remote location
  - Should reference this standard for main campus determinations as well
  - No discussion of any limitations on creation of new remote locations
    - Can add new remote locations as long as "primarily" engaged in providing inpatient care
- Reference to right to appeal an adverse determination
  - Unclear how this right intersects with judicial review preclusion

Relocations

- CMS purports to base its policy on the definition of “department,” which incorporates the physical facility (as well as the personnel and equipment)
  - Claims that therefore the location must remain “fixed”
- Overarching concern is with acquiring new physician practices
  - Fear is that, if relocate to a larger space, a site could bring in new physicians
- Must remain at site listed on 855
  - Specific down to the suite number (but no limitation as to how many interior walls can be torn down)
- CMS will entertain comments on limited exceptions

Relocations *(cont.)*

- CMS' explanation is unsatisfactory
  - The definition of "department" states:

  Department of a provider means a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. <u>A department of a provider comprises 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</u>. A department of a provider may not by itself be qualified to participate in Medicare as a provider under §489.2 of this chapter, and the Medicare conditions of participation do not apply to a department as an independent entity.

Relocations *(cont.)*

- CMS had the following to say about why it was adding this text:

  > We proposed this change because we believed it would help to clarify that we would make determinations with respect to entities considered in their role as sources of health care services and not simply as physical locations.

  67 Fed. Reg. at 50080 (Aug. 1, 2002)

- So why is the emphasis now flipped?

Relocations *(cont.)*

- If CMS is trying to prevent new physician practice acquisitions, then it can do so directly; prohibiting relocations is too blunt an instrument
  - Additionally, it allows for physician practice acquisitions and doesn't allow growth that doesn't require physician practice acquisitions
- Suggested comments include:
  - Relocations should be permitted generally
  - If limited to exceptions, should include:
    - Relocations once every 5 years to accommodate necessary renovations to space
    - Natural disasters
    - Growth in population of service area
    - Buildings that were under development when BiBA was passed

Relocations *(cont.)*

- In the meantime . . .
  - Don't relocate a facility if it requires changing an address
  - Check the 855 info your facility has furnished CMS to see what address is on file
  - Consider which facilities need to be expanded and determine whether that can be done without adding a new suite number

Service Lines

- CMS misinterprets the statute as fixing the “items and services” that can be furnished to those that were furnished as of the date of enactment of BiBA
  - Not true. It fixes the number of “departments” that can bill for OPPS items and services, but does nothing to limit which items and services can be furnished
- Creates a new concept of “clinical families”, as if that equates with the concept of “department”
  - Concern is with acquiring new physician practices that have a different clinical focus
- Creates potential for billing patients partially for OPPS services and partially for freestanding services for same visit

Service Lines *(cont.)*

- Possible comments to submit
  - Suggest that CMS should stick with limiting "departments" and not services, as is consistent with the plain meaning of the statute
  - Suggest that CMS focus on patient needs and not limit to new services, *e.g.*, if a cancer center seeks to expand from infusion therapy to include radiation therapy, it is in the interests of good patient care to allow the site to do so
- In the meantime . . .
  - Review all claims from the inception of OPPS pertaining to a site to see how many clinical families are represented in the site's claims

Service Lines *(cont.)*

- What does this mean for "under arrangements" billing for diagnostic services?
  - By statute, hospital diagnostic services can be furnished "under arrangements" to hospital outpatients
  - CMS previously acknowledged that hospitals can furnish diagnostic services in space that is not provider-based
  - Even with BiBA, the possibility remained open that hospitals could continue to furnish diagnostic services on an outpatient basis "under arrangements," even if the arrangement is with itself
  - CMS' limitation on new items and services, even if furnished in the same "department," calls into question whether new diagnostic under arrangements services will be excluded
  - Need clarification in comment letters

Changes of Ownership

- CMS explains that, unless the main provider changes hands, the change of ownership of a specific provider-based clinic nullifies its grandfathered status

Evidencing Grandfathered Status

- CMS implies that only sites that have been properly identified through information submitted on 855s will be allowed to claim provider-based status
- CMS proposes a voluntary attestation process that would allow hospitals to furnish the addresses of their provider-based sites and the clinical families of services furnished there
  - CMS acknowledges that it has no way of identifying this information solely from claims data

Evidencing Grandfathered Status *(cont.)*

- CMS is probably correct that it will need to rely on hospitals to furnish this info
- Comments could include:
  - The 855 is not the definitive source of info, especially since CMS' policy on relocations is new; therefore, CMS should not use the 855 info exclusively for determining what addresses identify provider-based locations
    - Note that failure to follow 855 notification rules could result in deactivation of a provider's billing number
  - Hospitals as well will find this task challenging and should be allowed to make reasonable assumptions about what services where furnished at which locations
  - Hospitals should be given sufficient time, perhaps 2 years to complete this exercise, and should be allowed to collect at the OPPS rate during the pendency of their review

Evidencing Grandfathered Status *(cont.)*

- In the meantime . . .
  - Hospitals should determine whether Epic or similar EMR system will allow them to determine what services (by CPT code) were furnished at specific sites <u>anytime</u> prior to the enactment of BiBA
  - Hospitals should make sure that management is aware that there will be this self-certification process that will have significant reimbursement and compliance implications

Billing for Non-Excepted Services

- CMS acknowledges that there are many challenges to creating a system to allow for billing under the otherwise applicable payment system
- CMS will not be ready until 2018 (at the earliest) to implement the payment mechanism required by the statute
  - CMS states it may need to create a new provider/supplier type
- CMS is seeking comments on changes needed to the enrollment form, claim form, and cost report to allow for the new system to occur in 2018

Billing for Non-Excepted Services *(cont.)*

- CMS' interim solution is to allow physicians to bill for these services as if furnished in freestanding space
  - Only applies to those services which would otherwise be classified as physician services, but for their being furnished in provider-based space
  - Hospitals can still separately bill for non-bundled clinical labs
- Alternatively, hospitals can re-enroll as a different supplier type
- CMS is interested in getting comments on how its policy will affect Stark, reassignment, and anti-markup compliance

Billing for Non-Excepted Services *(cont.)*

- CMS very expressly did not propose changing the Provider-Based Rule. This means that the following advantages should be maintained:
  - 340B status – patients will continue to be hospital "patients" treated in "provider-based space"
  - Bad debt should still be available
  - Data can still be collected for S-10 purposes
  - May be beneficial for UPL

Billing for Non-Excepted Services *(cont.)*

- Many, many questions:
  - What about differences in coverage between outpatient and physician office settings?
  - What about differences in bundling? This may actually be a benefit to hospitals.
  - How will outlier cost to charge ratios be calculated?
  - How will this affect hospital quality data reporting and value-based purchasing?
  - What will hospitals bill for in 2018 for services where there is no TC?
  - And then there are the Stark questions . . .

Stark Law Implications of Billing for Non-Excepted Services

- CMS 2016 Physician Fee Schedule Rule
  - Statement that a physician's use of a hospital's resources (e.g., facilities and personnel) when treating hospital patients is not remuneration when hospital and physician bill separately
    - Statement in response to Third Circuit decision in *Kosenske v. Carlisle HMA*
  - A physician's use of a hospital's resources when the physician bills for the service globally (i.e., for both the physician's services and hospital resources) constitutes remuneration that implicates the Stark Law

Stark Law Basics

- If a **physician** has a **financial relationship** (i.e., compensation arrangement) with an **entity** ..., then the physician may not make a **referral** to the entity for the furnishing of **designated health services** (e.g., outpatient hospital services) for which payment otherwise may be made under **Medicare** unless an **exception applies**
- Strict liability statute – intent doesn't matter
- Proscriptive statute – if an arrangement implicates the statute, then the arrangement must meet an exception
- Mechanical Approach – "if A then B"

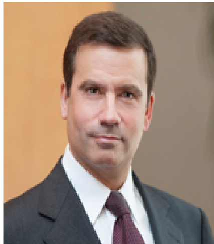
Possible Stark Law Exceptions

- Must meet all of the requirements of an exception; substantial compliance is not sufficient
  - Employment Exception – no written agreement required
  - New Timeshare Arrangement Exception
  - Personal Service Arrangements Exception
  - Fair Market Value Exception
  - Indirect Compensation Arrangement Exception
  - Except for the employment exception, the other exceptions require:
    - written agreement signed by parties; specify the services to be furnished; a term of at least 1 year; compensation that is set in advance, consistent with FMV and does not vary with volume or value of referrals

Have a Strategy for Compliance

- Identify those Provider-Based locations where non-excepted services will be furnished well in advance of effective date
- Identify universe of physicians who furnish non-excepted services at that location
- Understand the physician's relationship with the hospital
  - employee; member of an affiliated group; independent physician
- Educate the physicians as to the new requirements and prepare template agreements
- Establish methodology for determining payments to collected by hospital for use of resources/personnel

Questions?



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