Expanding 340B Participation: The Provider-Based Challenge

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Overview

- 340B Program Background
- Child Site Requirements
- Adding New Locations to the 340B Enrollment
- Provider-Based Requirements
- Case Studies
340B Program Background

- Section 340B of the Public Health Service Act (42 U.S.C. §256b)
- Implemented by Congress in 1992 through enactment of Public Law 102-585, Section 602
- Administered by Office of Pharmacy Affairs (OPA) at Health Resource and Services Administration (HRSA)
- Requires manufacturers to enter into agreement with HRSA to provide lower pricing on “covered outpatient drugs” to 340B covered entities
340B Program Background

- No official regulations on 340B program.
  - Guidance mostly through OPA FAQs, website, APEXUS guidance, HRSA policy statements, Federal Register publications, etc.

- But . . . watch for the long-awaited Mega Reg later in June 2014!
  - Patient definition guidance; contract pharmacy rules; child site guidance
340B Program Background

- Eligible Hospital Entities (requiring qualifying DSH payment percentages)
  - Acute-care Hospitals (11.75%)
  - Children’s Hospital (11.75%)
  - Cancer Hospitals (11.75%)
  - SCHs (8%)
  - Rural Referral Centers (8%)
  - CAHs (no DSH requirement)

- Also other types of eligible entities
  - Which can be enrolled as either Covered Entities or as child sites of other Covered Entities
340B Program Background

- Eligible Hospital Entities must:
  - Be owned or operated by a unit of State or Local government;
  - Be a non-profit hospital formally granted government powers (generally occurs in other states); or
  - Be a non-profit hospital with a contract with State or Local government to provide health care services to low-income who are not entitled to Medicare or eligible for State Medicaid

- The required contracts can be a variety of government entities and are fairly basic
Child Site Requirements

To be a child site of a covered entity, the child site must:

- Be an outpatient location

- Appear on the most recently filed hospital cost report
  - This requires the location to be a provider-based location of the covered entity (hospital)
  - Can not appear on cost report until a patient treated there
  - Potential for long enrollment lags
Adding New Locations to the 340B Enrollment

- Can only add new child sites during first fifteen days of each calendar quarter
  - More restricted procedure than historically

- New child site can participate in 340B program at the beginning of the quarter following registration
Adding New Locations to the 340B Enrollment

- Combination of cost-report requirement and quarterly enrollment requirement can lead to lags in effective date of enrollment

- Example:
  - Treat first patient in new clinic January 12, 2014
  - Hospital’s cost year is calendar year, so cost year ends December 31, 2014
  - Cost report filed May 15, 2015
  - Earliest enrollment is July 1-15, 2015
  - Earliest 340B effective date is October 1, 2015
Adding New Locations to the 340B Enrollment

- Online registration through OPA for new child site locations
  - OPA will verify main provider qualification from cost report
  - Also must submit certain cost report worksheets including a working trial balance or other similar budget document showing costs of the new location
  - May need to work with OPA on the specifics of your budget documents to determine what OPA needs

- Covered entity responsibility to meet deadlines for enrollment, despite documentation questions
Adding New Locations to the 340B Enrollment

- All child site locations must register with OPA prior to providing any 340B drugs
  - Case by case determination whether clinics relocating from within the four walls to off-site must “re-register” with OPA

- Each service line provided at an off-site child site must register separately with OPA

- Service lines within the four walls of the hospital do not have to register separately
Adding New Locations to the 340B Enrollment

- “Off-campus” (provider-based) vs. “Off-site” (340B)
  - 250 yard requirement for provider-based
  - Outside the four walls of the main provider for 340B
- Could be “on-campus” for provider-based and “off-site” for 340B
- Outside the four walls is stricter definition than “on-campus”
  - Mailing address; roads; walkways
Provider-Based Requirements

- The requirements for achieving provider-based status for a location are set forth in the Medicare regulations at 42 CFR § 413.65.

- The determination of provider-based status affects the manner in which services are billed to the Medicare program.
Provider-Based Requirements

What is Provider-Based Status?

- **General Rule** – Provider-based requirements apply to a facility if its status as a provider-based vs freestanding affects any of the following:
  
  i. Medicare/Medicaid payment amounts
  ii. Scope of benefits available to a Medicare beneficiary in the facility or
  iii. Deductible or coinsurance liability of a Medicare beneficiary for services furnished in the facility

- All provider-based requirements apply to “off-campus” facilities
- A subset of the provider-based requirements apply to on-campus facilities (on-campus – within 250 yards of a hospital’s “main building”)
Provider-Based Requirements
Advantages of Provider-Based Status

- Medicare/Medicaid payment amounts
- Medicare coverage
- 340B drug discount program eligibility
- Main provider/remote location DSH and IME payments
- Inclusion in main provider’s third party payer contracts
- Counting residents for direct GME and IME payments
Provider-Based Requirements
Disadvantages of Provider-Based Status

- Medicare conditions of Participation (CoPs) for hospitals apply
- Medicare billing
- Life Safety Code applies
- EMTALA
- Medicare payments for physician services reduced
- Written notices to beneficiaries required for off-campus outpatient departments
- Commercial payers refuse to pay facility fees
Provider-Based Requirements
Attestation Process

- Voluntary attestation process
- Mandatory to meet all elements of regulation
- Different attestation process for on-campus and off-campus
- Provider-based status is granted to a location not a service
Provider-Based Requirements

- Campus – the physical area immediately adjacent to the provider’s main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main building and any other areas determined on an individual case basis, by the CMS regional office, to be part of the campus
Provider-Based Requirements
On-Campus Facility

- **Licensure** – Main provider and facility are operated under same license (except if state requires separate licensure or prohibits common licensure)

- **Clinical services** – Clinical services of facility and main provider are integrated:
  - Facility professional staff have clinical privileges at main provider
  - Main provider maintains same monitoring and oversight of the facility as other departments
  - Medical director of facility maintains same reporting relationship with CMO as other departments and is under same type of supervision and accountability as any other director
  - Medical staff committees at main provider are responsible for medical activities in facility
  - Facility medical records are integrated (unified retrieval system)
  - Inpatient and outpatient services are integrated
Provider-Based Requirements
On-Campus Facility

• **Financial integration** – Financial operations of facility are fully integrated within financial system of main provider:
  - Shared income and expenses between main provider and facility
  - Hospital department costs are reported in a cost center of provider
  - Provider-based facility costs are reported in appropriate cost center(s) of main provider
  - Financial status of facility is incorporated and readily identified in main provider’s trial balance

• **Public awareness**
  - Facility is held out to the public and other payers as part of main provider
  - When patients enter facility, they are aware that they are entering the main provider and are billed accordingly
Provider-Based Requirements
On-Campus Facility

• Provider-based obligations
  – EMTALA
  – Physician services are billed with correct site-of-service
  – Hospital outpatient departments must comply with all terms of hospital’s provider agreement
  – Physicians comply with federal non-discrimination provisions
  – Hospital outpatient departments treat all Medicare patients, for billing purposes, as hospital outpatients; department must not treat some Medicare patients as hospital outpatients and others as physician office patients
  – Three-day payment window policy applies
  – Hospital outpatient department must meet applicable health and safety rules in Medicare CoPs
Provider-Based Requirements
On-Campus Facility

• **Under arrangements** – Facility cannot furnish all patient care services under arrangement

• **Joint ventures** – In order for a facility operated as a joint venture to be provider-based, facility must comply with all of the following conditions:
  - Be partially owned by at least one provider
  - Be located on main campus of a provider that is a partial owner
  - Be provider-based to that one provider on whose campus the facility is located
  - Meet all other applicable provider-based requirements, including the financial integration requirement (shared income and expenses, facility costs reported in hospital cost center, and facility’s status is incorporated and readily identified in hospital’s trial balance)
Provider-Based Requirements
Off-Campus Facility

- Facility is operated under the ownership and control of main provider:
  - Business enterprise that constitutes the facility is 100 percent owned by main provider
  - Facility and main provider have same governing body
  - Facility and main provider are operated under same organizational documents
  - Main provider has final responsibility for administrative decisions, final approval for contracts with outside parties, final approval for personnel actions, final responsibility for personnel policies, and final approval for medical staff appointments in the facility
Provider-Based Requirements
Off-Campus Facility

• **Administration and supervision** – Reporting relationship between facility and main provider has same frequency, intensity, and level of accountability as other departments of hospital:
  - Facility is under direct supervision of main provider
  - Facility is operated under same monitoring and oversight by provider as any other department and operated as any other department with respect to supervision and accountability; facility director maintains reporting relationship with manager at main provider that has same frequency, intensity, and level of accountability as other departments and is accountable to governing body of main provider
  - Specified administrative functions of facility are integrated with those of main provider
Provider-Based Requirements
Off-Campus Facility

• Location
  – Facility is located within 35-mil radius of main provider
  – Facility is operated by a hospital/CAH that has a DSH adjustment greater than 11.75%, and is owned or operated by state or local government or meets other conditions
  – 75/75 patient population tests:
    i. 75% of facility’s patients reside in same zip code areas as 75% of main provider’s patient’s; or
    ii. 75% of facility’s patients who require inpatient care received such care from main provider
  – Rural children’s hospital NICU
Provider-Based Requirements
Off-Campus Facility

- Additional obligation
  - **Written notice of beneficiary liability** – Hospital must provide written notice to beneficiary, before delivery of services (EMTALA patient excepted):
    - Amount of beneficiary’s potential financial liability, or if the exact type and extent of care needed are not known, an explanation that the beneficiary will incur a coinsurance liability to the hospital that he/she would not incur if the facility were not provider-based
    - an estimate based on typical or average charges for visits to the facility and
    - a statement that the patient’s actual liability will depend on the actual services furnished by hospital
  - Notice must be one beneficiary can read and understand
Provider-Based Requirements
Off-Campus Facility

- **Management contracts** – A facility that is operated under a management contract must meet the following conditions:
  - Main provider (or an organization that also employs staff of main provider and that is not management company) employs staff directly involved in delivery of patient care
    - Exceptions – Personnel who solely furnish administrative services; and professionals who furnish patient care services of a type paid under Medicare physician fee schedule (physicians, non-physician practitioners)
  - Administrative functions of the facility are integrated with those of the main provider
  - Main provider has significant control over facility operations
  - Management contract is held by main provider itself
Case Study #1

- Hospital provider is considering converting a leased physician office that provides multiple types of services (e.g., primary care clinic, wound care, etc.) into a hospital-based department in order to take advantage of 340B pricing
- How does it happen?
Case Study #2

- Hospital provider has an on-campus provider-based location across the street from the main hospital that offers three different patient services. The main hospital is a DSH-qualifying 340B covered entity. It wants to add a new service line that qualifies for 340B.
- What are its options?
Questions?

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