Strategic Planning for Physician Practice Acquisitions in the Post-Site Neutrality Payment Era

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I. FINANCIAL PLANNING FOR OUTPATIENT HOSPITAL VS. FREESTANDING PHYSICIAN PRACTICE.

A. Payment Implications. There are a variety of payment implications and differences between hospital provider-based and freestanding/non-hospital settings under the Medicare (and often Medicaid and commercial payor programs), including:

1. Medicare generally pays a higher aggregate payment for diagnostic and therapeutic services furnished in the hospital outpatient department setting compared to the same services performed in other provider/supplier settings. This is generally true even though physician fees are reduced for professional services furnished in hospital outpatient departments (lower practice expense relative value units) in what is known as the "site of service differential." Thus, the total payment (facility fee plus reduced physician fee) is generally more for a service furnished in provider-based department of a hospital than for the same service furnished in a freestanding physician clinic.

    a. Hospital facility fees for outpatient department services may include use of the following: (i) hospital facilities, including the use of the emergency room; (ii) services of nurses, nonphysician anesthetists, psychologists, technicians, therapists and other aides; (iii) medical supplies, such as gauze, oxygen, ointments and other supplies used by physicians or hospital personnel in the treatment of outpatients; (iv) surgical dressings; (v) splints, casts, and other devices used for reduction of fractures and dislocations; (vi) prosthetic devices; and (vii) leg, arm, back and neck braces, trusses, and artificial legs, arms and eyes. *See* Medicare Benefit Policy Manual (Pub. 100-02), Chapter 6, Section 40.

2. A hospital may count medical residents who train in hospital outpatient departments for purposes of Medicare direct graduate medical education payments and indirect medical education payments without regard to the requirements for counting residents' training time in non-provider settings.

3. Bad debt is reimbursable in provider-based space, but is not reimbursable to physician offices.

4. Uncompensated care in provider-based space can count towards the hospital's uncompensated care costs that drive disproportionate share hospital payments.

5. Unless contracts specifically exclude them, all hospital outpatient departments will be included within the scope of a hospital's third-party payer contracts, but hospital-owned physician clinics will require separate contracts.

6. Hospitals may access discounted drug pricing through 340B program. Patients registered as outpatients at provider-based locations of hospitals eligible to participate in 340B may be included in the population that benefits from such discounts.

B. Coverage – Generally.

1. Medicare. For certain services, Medicare will only cover and pay if the services are performed in a hospital or other Medicare-certified setting, versus a non-certified, freestanding entity.

a. For example, Medicare only covers and pays for partial hospitalization services if provided in a hospital outpatient department or in a community mental health center. 42 U.S.C. § 1395x(s)(2)(B); 42 C.F.R. § 410.110.

2. Commercial. Commercial payers and some state Medicaid sometimes refuse to cover facility fees related to physician services furnished in hospital outpatient departments.

C. Medicare Billing. Hospital services performed in outpatient departments are billed to Medicare contractors on form UB-04 (CMS-1450). Physician services performed in outpatient departments are billed to Medicare contractors on CMS-1500s claim forms. This is sometimes referred to as a "split bill." In comparison, services performed in a freestanding clinic only result in one bill. Physician services provided in a freestanding clinic are billed to Medicare contractors on form 1500s; there is no facility fee.

D. Certain Other Payment/Billing Implications of Provider-Based Status.

1. Prohibition on Hospital Outpatient Unbundling. The Medicare outpatient services unbundling rule prohibits Medicare payment for non-physician services to a hospital outpatient during an encounter by a provider or supplier other than the hospital, unless the services are furnished under an arrangement with the hospital. *See* 42 C.F.R. § 410.42.

2. "Incident To" Services. The Medicare rules expressly prohibit Medicare coverage of the services of physician-employed auxiliary personnel furnished to hospital outpatients as services "incident to" physicians' services. 42 C.F.R. § 410.26(b)(1). There is a related part B concept known as the "shared/split" service under which certain non-physician practitioners can have their services combined with a physician's services in order to generate a single service under the physician's CMS-1500. Shared/split services are permissible in the provider-based hospital outpatient department as well as the inpatient and emergency department settings. Medicare Claims Processing Manual (CMS Pub. 100-04), Ch. 12, Section 30.6.1.B.

E. Medicare Conditions of Participation.

1. The Medicare Conditions of Participation ("CoPs") for Hospitals apply to hospital outpatient departments, which must satisfy the requirements for medical staff, physical environment, and outpatient services. See 42 C.F.R. §§ 482.22, 482.41 and 482.54. These CoPs do not apply to freestanding physician clinics. As a result, hospital outpatient departments generally are more costly to construct and operate than freestanding physician clinics.

3. Some provider-based departments, if they are "dedicated emergency departments" ("DEDs") must also comply with the patient anti-dumping or EMTALA law, discussed at Section VI, below.

II. IMPACT OF SITE-NEUTRALITY (STATUTORY AND REGULATORY CHANGES)

A. The Bipartisan Budget Act of 2015 was passed on November 2, 2015.

B. Section 603 of the legislation precludes payment under OPPS for any off-campus, provider-based clinics that had not provided any services prior to the date of the statute's enactment (November 2, 2015). These pre-existing provider-based facilities are known as "excepted." This will apply to all new physician enterprises that are acquired and converted to provider-based status off-campus, with a couple of exceptions

1. An exception applies for dedicated emergency departments (DEDs), noted above.

2. An exception for provider-based departments within 250 yards of a "remote location" (inpatient facility) of the hospital.

C. New provider-based clinics that are not DEDs or within 250 yards of a remote location must be constructed "on campus" to avoid the Section 603 payment cuts.

D. CMS has implemented via Federal Register preamble certain policy considerations.

1. Other than for extraordinary circumstances, hospitals cannot relocate grandfathered, provider-based relocations.

2. CMS has created a new payment system that allows hospitals to bill for non-grandfathered sites on a CMS 1450, but pays them at a rate that is meant to be equivalent to the physician fee schedule rate.

E. The most recent payment reduction reimburses non-exempt PBDs at 40% of the OPPS rate. This rate cut applies to all off-campus outpatient departments of a provider (OCODP).

F. In 2019, CMS by regulation expanded the site-neutrality payment reductions to all OCODPs (whether excepted or not) with respect to physician clinic services. This regulatory payment reduction was challenged by the American Hospital Association and other plaintiffs. At the time of the drafting of this outline, the District Court had not ruled on the challenge.

III. PRACTICAL CHALLENGES TO CONVERTING A FORMER PHYSICIAN PRACTICE TO PROVIDER-BASED HOSPITAL OUTPATIENT DEPARTMENT.

A. To be a Hospital outpatient department, the facility must meet the "provider-based" requirements found at 42 C.F.R. § 413.65, and are further explained in Program Memorandum (Intermediaries) Transmittal A-03-030 (April 18, 2003), with an accompanying Sample Attestation Form.

B. The provider-based requirements generally apply for purposes of both Medicare and Medicaid program payments. Accordingly, Medicaid program payments for services performed in a facility subject to the provider-based requirements but failing to meet all such applicable requirements will not be made at Medicaid hospital rates unless the State revises its State plan to permit such payments. *See* 65 Fed. Reg. 18434, 18506 (April 7, 2000); 67 Fed. Reg. 49981, 50083 (August 1, 2002).

C. Since October 1, 2002, CMS has not required providers to obtain an affirmative provider-based determination from their CMS Regional Offices before treating a facility as provider-based for Medicare/Medicaid payment purposes. *See* 67 Fed. Reg. 49981, 50084-085 (August 1, 2002); Program Memorandum (Intermediaries) Transmittal A-03-030 (April 18, 2003). There is one possible exception to this general rule. The provider-based regulations include that off-campus departments that "provide physician services of a kind normally provided in a physician's office"

are presumed to be freestanding unless determined to be provider-based. 42 C.F.R. § 413.65(b)(4). This provision has not been the subject of any formal interpretation by CMS or decisional law interpreting this "presumption." However, in the 2014 OPPS final rule in the context of a discussion about freestanding physician practices being converted to hospital off-campus outpatient departments, CMS affirmatively stated that it has not required hospitals to seek from CMS a determination of provider-based status since October 1, 2002. *See* 78 Fed. Reg. 74826, 75061 (December 10, 2013). Even for other facilities, however, there is some potential ambiguity as to the possible negative consequences for a hospital that does not obtain a positive provider-based determination for a facility and thereafter CMS determines that the facility does not satisfy the applicable provider-based requirements. *See* Section III.F.2.b. herein.

D. Facilities for which provider-based determinations are made include departments of a provider (outpatient departments), remote locations of a hospital, and satellite facilities.

E. If the Hospital is planning to utilize the facility as something other than a hospital outpatient department, a provider-based determination will not be made, the payment rules, above, generally will not be applicable. These other uses to which a former physician services operation may be converted[1] include:

1. Ambulatory surgery centers (ASCs);

2. Comprehensive outpatient rehabilitation facilities (CORFs);

3. Rural health clinics (RHCs) affiliated with hospitals having 50 or more beds (independent RHCs and hospital-based RHCs with more than 50 beds are both paid based on an all-inclusive per-visit rate; an RHC that is provided-based to a hospital with less than 50 beds is eligible to receive an exception to the all-inclusive, per-visit payment limit);

4. Independent diagnostic testing facilities ("IDTFs") that furnish only services paid under a fee schedule; and

5. End stage renal disease facilities (for nephrology practices).

[1] It should be noted that this is not an exclusive list of the types of providers that will not receive CMS attention in the context of provider-based status attestations. They also include: home health agencies (HHAs); skilled nursing facilities (SNFs); hospices; and rehabilitation therapy and excluded inpatient rehabilitation units, but it is highly unlikely that a physician organization would be constructed in such a way as to provide these services, even with extensive modification.

IV. GATING ISSUES: PROVIDER-BASED STATUS REQUIREMENTS (42 C.F.R. § 413.65(d) AND (e)).

A. Providers are cautioned to review all of the provider-based status requirements found a 42 C.F.R. 413.65, as they will all be applicable to the new facility or organization. Many of the requirements can be satisfied through administrative action at the hospital to integrate the physician enterprise within the hospital, including: clinical integration, public awareness and financial integration.

B. Other of the requirements will be seen as "gating issues," that is, if these conditions cannot be met, then the organization must be freestanding or enrolled as some other type of entity, such as those referenced in Section III.E, above.

C. Several of the requirements that cannot be addressed through policy or reorganization:

1. Licensure. The department of the provider, remote location of a hospital, or the satellite facility and the main provider are operated under the same license, except in areas where the State requires a separate license, or in States where State law does not permit licensure of the provider and the prospective provider-based facility under a single license. Note that State licensure requirements often include physical plant conditions.

a. In a 2012 decision, the Department of Health and Human Services' Departmental Appeals Board sustained an administrative law judge's determination that the denial by CMS of provider-based status for three off-campus facilities affiliated with a hospital was consistent with the provider-based status requirements. CMS had denied provider-based status to the three facilities as they were not included on the hospital's license. *Union Hospital, Inc.*, DAB Dec. No. 2463 (June 11, 2012).

2. Location. There are different methods of proving that the off-campus facility is located in close enough proximity to the main provider to be provider-based.

a. 35 mile rule. The facility is located within a 35-mile radius of the campus of the hospital that is the potential main provider. The 35 mile rule is a straight-line test, not a road-driven test.

b. 75/75 alternative. The facility demonstrates a high level of integration with the main provider by showing that it meets all of the other provider-based criteria and demonstrates that it serves the same patient population as the main provider, by submitting records showing that, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with CMS, and for each subsequent 12-month period–

i. At least 75 percent of the patients served by the facility reside in the same zip code areas as at least 75 percent of the patients served by the main provider; and

ii. At least 75 percent of the patients served by the facility who required the type of care furnished by the main provider received that care from that provider.

c. Disproportionate share alternative.

d. Children's hospital neonatal intensive care unit exception.

e. A facility may satisfy the location condition only if it is located in the same State as the main provider or, when consistent with the laws of both States, in adjacent States.

3. Life Safety Code and Other Health and Safety Rules. Hospital outpatient departments must meet applicable hospital health and safety rules. Specifically, "[t]he hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association" (42 C.F.R. § 482.41(b)(1)(i)). In Survey and Certification Memorandum S&C-11-05-LSC to State Survey Agency Directors from the Director, CMS Survey and Certification Group (December 17, 2010, revised February 18, 2011), CMS revised the Medicare State Operations Manual, Appendices A, I and W, to expressly describe the specific Life Safety Code requirements that apply to various types of provider-based facilities.

V. IF THE PHYSICIAN ENTERPRISE ACCEPTS A SIGNIFICANT NUMBER OF PATIENTS FOR EMERGENCY SERVICES WITHOUT APPOINTMENT, OR IS HELD OUT AS OFFERING EMERGENCY SERVICES, THEN THE REQUIREMENTS OF THE EMERGENCY MEDICAL TREATMENT AND LABOR ACT LIKELY WILL APPLY.

A. EMTALA.

1. On-campus outpatient departments. The EMTALA screening and stabilization or transfer obligations apply to a hospital on-campus facility treated as an outpatient department. These obligations include the general EMTALA requirements, signage/posting requirements, maintaining a list of on-call physicians, maintaining a central log and records of transfers to and from the facility, and reporting improper transfers.

2. Off-campus outpatient departments.

a. The EMTALA screening and stabilization or transfer obligations apply to a hospital off-campus facility treated as an outpatient department only if it is considered a "dedicated emergency department" as defined at 42 C.F.R. § 489.24. A "dedicated

emergency department" is defined as a hospital facility that meets at least one of three conditions: (i) the facility is licensed by the State in which it is located under applicable State law as an emergency room or emergency department; (ii) the facility is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or (iii) during the calendar year immediately preceding the calendar year in which a determination is made, based on a representative sample of patient visits that occurred during that calendar year, the facility provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment. An off-campus dedicated emergency department is required to comply with the same EMTALA requirements as on-campus outpatient departments.

b. An outpatient department that is not a "dedicated emergency department" is not subject to EMTALA. For a hospital outpatient department that is not a "dedicated emergency department," if an individual would present for emergency care, it would be appropriate for the department to call an emergency medical service if it is incapable of treating the patient, and to furnish whatever assistance it can to the individual while awaiting the arrival of emergency medical service personnel. Hospitals are required to have appropriate protocols in place for dealing with individuals who come to off-campus facilities seeking emergency care. 68 Fed. Reg. 53221, 53248-49 (Sept. 9, 2003).

3. There are financial benefits if the facility will be treated as a DED, including that it will receive full OPPS reimbursement without the limitations of Section 603 of the BiBA.

VI. WILL THE PHYSICIAN ENTERPRISE BE ABLE TO CONNECT TO AN ACCOUNTABLE CARE ORGANIZATION OR PARTICIPATE IN ANOTHER DEMONSTRATION PROGRAMS?

A. Introduction.

1. Hospitals incorporating physician enterprises have additional flexibilities if these operations can connect to a hospital-affiliated accountable care organization, or "ACO." This includes the ability to provide special incentives to physicians and patients receiving services at the new enterprise.

2. If the enterprise is part of an ACO, there will be incentives to contain costs, and the organization may not want to be treated as a hospital outpatient department to avoid additional costs, and earn new "shared savings."

3. ACOs were created by Section 3022 of the Affordable Care Act. ACOs are organizations comprised of various providers and suppliers who are responsible for the care of a patient population that is assigned to them. Depending upon the type of model that a particular ACO is enrolled in, it may have "two sided risk," whereby it *owes* the Medicare program money if Medicare's expenses for the patient population assigned to the ACO over the course of a year are higher than a benchmark. A portion of that excess is payable back to the Medicare program.

4. There are a number of other demonstration programs that operate similarly to ACOs, including:

    a. Bundled Payments for Care Improvement Advanced Model

    b. Comprehensive ESRD Care (CEC) Model (LDO arrangement)

    c. Comprehensive ESRD Care (CEC) Model (non-LDO two-sided risk arrangement)

    d. Comprehensive ESRD Care (CEC) Model (non-LDO one-sided risk arrangement)

    e. Comprehensive Primary Care Plus (CPC+) Model

    f. Medicare Accountable Care Organization (ACO) Track 1+ Model

    g. Medicare Shared Savings Program Accountable Care Organizations – Track 1, 2, 3

    h. Next Generation ACO Model

    i. Oncology Care Model (OCM) (one-sided Risk Arrangement)

    j. Oncology Care Model (OCM) (two-sided Risk Arrangement)

    k. Vermont Medicare ACO Initiative (as part of the Vermont All-Payer ACO Model)

    l. Maryland Primary Care Program

    m. Independence at Home Demonstration

5. For physicians participating in any of these programs, there are negative financial consequences for increases in Medicare spending. Thus, if the technical component of a physician's services were previously billed under the physician fee schedule, but then are billed under the outpatient fee schedule, there would be increased costs associated with those services. Unless there are reduced costs from other service providers treating that physician's patients, some of the increased revenue associated with the

outpatient facility fee would be offset by the repayment due as a result of participation in the demonstration program.