Thus, Medicare has had limited recourse when hospital outpatient therapeutic ("incident to") services are not furnished in compliance with State law.

In 2009, the Office of the Inspector General (OIG) issued a report entitled "Prevalence and Qualifications of Nonphysicians Who Performed Medicare Physician Services" (OEI–09–06–00430) that considered, in part, the qualifications of auxiliary personnel providing "incident to" physician services. After finding that services were being provided and billed to Medicare by auxiliary personnel ". . . who did not possess the required licenses or certifications according to State laws, regulations, and/or Medicare rules," the OIG recommended that we revise the "incident to" rules to, among other things, "require that physicians who do not personally perform the services they bill to Medicare ensure that no persons except . . . nonphysicians who have the necessary training, certification, and/or licensure pursuant to State laws, State regulations, and Medicare regulations personally perform the services under the direct supervision of a licensed physician." We are proposing amendments to our regulations in order to address this recommendation.

To ensure that the practitioners and other personnel providing hospital outpatient therapeutic services to Medicare beneficiaries incident to a physician's or nonphysician practitioner's service do so in accordance with the requirements of the State in which the services are furnished, and to ensure that Medicare payments can be recovered when such services are not furnished in compliance with the State law, we are proposing to add a new condition of payment to the "incident to" regulations at § 410.27, Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions. Specifically, we are proposing to add a provision under a new paragraph (a)(1)(vi) under § 410.27 to provide that "Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service . . . if they are furnished "In accordance with applicable State law." The proposed policy would recognize the role of States in establishing the licensure and other qualifications of physicians and other health care professionals for the delivery of hospital (or CAH) outpatient therapeutic services.

This proposal is consistent with other areas of the Medicare program where CMS defers to State rules regarding the delivery of hospital services. For example, the hospital conditions of participation (CoPs) at 42 CFR 482.12(c)(2) defer to State law in determining who can admit patients as inpatients of a hospital: "Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital." The CoP also provides that, "If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section (that lists practitioners that must care for Medicare patients), that patient is under the care of a doctor of medicine or osteopathy." Thus, in determining who may admit inpatients to a hospital, Medicare defers to State law rules. Also, as we stated in a recent rule addressing credentialing and privileging and telemedicine services under the CoPs (77 FR 29047): "CMS recognizes that practitioner licensure laws and regulations have traditionally been, and continue to be, the provenance of individual States, and we are not seeking to preempt State authority in this matter." We believe it is appropriate to similarly require that all hospital outpatient services furnished incident to a physician's or nonphysician practitioner's services be furnished in accordance with State law requirements. As evidenced by these examples, throughout the Medicare program the qualifications required for the delivery of health care services are generally determined with reference to State law. In addition to the health and safety benefits we believe would accrue to the Medicare patient population, this approach would assure that Federal dollars are not expended for services that do not meet the standards of the States in which they are being furnished, and provides the ability for the Federal government to recover funds paid where services and supplies are not furnished in accordance with State law.

This proposal would not impose any new requirements on hospitals billing the Medicare program because practitioners and other personnel furnishing services in a given State would already be required to comply with the laws of that State. This regulatory change would simply adopt the existing requirements as a condition of payment under Medicare. Codifying this requirement would provide the Federal government with a clear basis to deny a claim for Medicare payment when services are not furnished in accordance with applicable State law, and the ability to recover funds, as well as assure that Medicare pays for services furnished to beneficiaries only when the services meet the requirements imposed by the States to regulate health care delivery for the health and safety of their citizens. We welcome public comments on this proposal.

3. Technical Correction

In our review of § 410.27, we noted that paragraph (a) defines therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service as "all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals that cannot be self-administered." Section 1861(s)(2)(B) of the Act describes these services as "hospital services (including drugs and biologicals which are not usually self-administered by the patient) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services." The statute includes in this benefit category "drugs and biologicals which are not usually self-administered by the patient." We are proposing to make a technical correction that would amend the description of these drugs and biologicals at § 410.27(a) to more appropriately reflect the statutory language. Specifically, we are proposing to delete the phrase "drugs and biologicals that cannot be self-administered" and replace it with the phrase "drugs and biologicals which are not usually self-administered." Under this proposed technical correction, the language of § 410.27(a) would read, "Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service, which are defined as all services and supplies furnished to hopital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals which are not usually self-administered. . . ."

D. Collecting Data on Services Furnished in Off-Campus Provider-Based Departments

In recent years, the research literature and popular press have documented the increased trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital, and the resultant increase in the delivery of physicians' services in a hospital setting (for example, we refer readers to

Ostrom, Carol M., "Why you might pay twice for one visit to a doctor," *Seattle Times,* November 3, 2012, and O'Malley, Ann, Amelia M. Bond, and Robert Berenson, *Rising hospital employment of physicians: better quality, higher costs?* Issue Brief No. 136, Center for Studying Health System Change, August 2011). When a Medicare beneficiary receives outpatient services in a hospital, the total payment amount for outpatient services made by Medicare is generally higher than the total payment amount made by Medicare when a physician furnishes those same services in a freestanding clinic or in a physician office. As more physician practices become hospital-based, news articles have highlighted beneficiary liability for an additional "facility fee," which is the payment Medicare makes when services are furnished in a hospital in addition to the payment to the physician. MedPAC has questioned the appropriateness of increased Medicare payment and beneficiary cost-sharing when physicians' offices become hospital outpatient departments and has recommended that Medicare pay selected hospital outpatient services at the Medicare Physician Fee Schedule (MPFS) rates (MedPAC March 2012 Report to Congress; "Addressing Medicare Payment Differences across Settings," presentation to the Commission on March 7, 2013).

The total payment (including both Medicare program payment and beneficiary cost-sharing) generally is higher when outpatient services are furnished in the hospital outpatient setting rather than a freestanding clinic or a physician office. Both the OPPS and the MPFS establish payment based on the relative resources involved in furnishing a service. In general, we expect hospitals to have overall higher resource requirements than physician offices because hospitals are required to meet the conditions of participation, to maintain standby capacity for emergency situations, and to be available to address a wide variety of complex medical needs in a community. When services are furnished in the hospital setting such as in off-campus provider-based departments, Medicare pays the physician a lower facility payment under the MPFS, but then also pays the hospital under the OPPS. The beneficiary pays coinsurance for both the physician payment and the hospital outpatient payment. The term "facility fee" refers to this additional hospital outpatient payment.

Upon acquisition of a physician practice, hospitals frequently treat the practice locations as off-campus provider-based departments of the hospital and bill Medicare for services furnished at those locations under the OPPS. (For further information on the provider-based regulations at § 413.65, we refer readers to *http://www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol2/pdf/CFR-2010-title42-vol2-sec413-65.pdf.* Since October 1, 2002, we have not required hospitals to seek from CMS a determination of provider-based status for a facility that is located off campus. We also do not have a formal process for gathering information on the frequency, type, and payment for services furnished in off-campus provider-based departments of the hospital.

In order to better understand the growing trend toward hospital acquisition of physician offices and subsequent treatment of those locations as off-campus provider-based outpatient departments, we are considering collecting information that would allow us to analyze the frequency, type, and payment for services furnished in off-campus provider-based hospital departments. We have considered several potential methods. Claims-based approaches could include creating a HCPCS modifier that could be reported with every code for services furnished in an off-campus provider-based department of a hospital on the CMS–1500 claim form for physician services and the UB–04 (CMS form 1450) for hospital outpatient claims. In addition, we have considered asking hospitals to break out the costs and charges for their provider-based departments as outpatient service cost centers on the Medicare hospital cost report, form 2552–10. We note that some hospitals already break out these costs voluntarily or because of cost reporting requirements for the 340B Drug Discount Program but this practice is not consistent or standardized. We are inviting public comments on the best means for collecting information on the frequency, type, and payment for services furnished in off-campus provider-based departments of hospitals.

XI. Proposed CY 2014 OPPS Payment Status and Comment Indicators

A. Proposed CY 2014 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and also whether particular OPPS policies apply to the code. The complete list of the proposed CY 2014 status indicators and their definitions is displayed in Addendum D1 on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* The proposed CY 2014 status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* The proposed changes to CY 2014 status indicators and their definitions are discussed in detail below.

For CY 2014, we are proposing to create a new status indicator "J1" to identify HCPCS codes that are paid under a comprehensive APC. A claim with the new proposed status indicator "J1" will trigger a comprehensive APC payment for the claim. The comprehensive APCs that we are proposing to establish are described in detail in section II.A.2.e. of this proposed rule.

For CY 2014, we are proposing to delete status indicator "X" and assign ancillary services that are currently assigned status indicator "X" to either status indicator "Q1" or "S". First, services that are proposed to be assigned status indicator "Q1" include many minor diagnostic tests that are generally ancillary to and performed with another service. However, services that are proposed to be assigned to status indicator "Q1" also may be performed alone. Given the nature of these services and their role in hospital outpatient care, we believe that when these services are performed with another service they should be packaged, but that they should be separately paid when performed alone. Therefore, we believe it is appropriate to conditionally package all ancillary services that are currently assigned to status indicator "X," and are proposing to assign them to status indicator "Q1." We also are proposing that preventive services currently assigned status indicator "X" continue to receive separate payment in all cases and be assigned status indicator "S" for CY 2014. These proposed changes are discussed in greater detail in section II.A.3. of this proposed rule. In addition, we are proposing to revise the definition of status indicator "Q1" by removing status indicator "X" from the packaging criteria, so that codes assigned status indicator "Q1" are STV-packaged, rather than STVX-packaged, because status indicator "X" is proposed for deletion.