Expiration of the “Grandfather Provision” for Anatomic Pathology

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Synopsis

In 1999, Medicare eliminated Part B reimbursement for independent laboratories providing anatomic pathology technical component (TC) services on behalf of hospital inpatients and outpatients. Thirteen years later, on June 30, 2012, this reimbursement change took full effect for all independent laboratories due to the expiration of a grandfathering provision that was included in the 1999 regulation (Grandfather Provision). The Grandfather Provision allowed reimbursement for these services to continue beyond the elimination of separate Part B reimbursement for those independent laboratories that were established and providing these services prior to June 22, 1999. In the period between June 22, 1999, and June 30, 2012, many independent pathology laboratories and hospitals maintained relationships for outsourced pathology services that did not necessitate compensation. As a result of the expiration of the Grandfather Provision, those hospitals that previously outsourced their anatomic pathology TC services to an independent laboratory have been forced to evaluate alternatives for obtaining these services. This article presents a brief history of Medicare reimbursement changes applicable to the anatomic pathology TC. In addition, it explores historical and prospective structures for obtaining these services, focusing on new issues hospitals must consider as a result of the expiration of the Grandfather Provision.

The Clinical Service

Pathology is not a typical medical specialty from an operational perspective. Hospital attorneys who may be well versed in typical medical and surgical specialty operations are required to learn a new language when it comes to pathology. An overview and background of some key terms will establish a foundation for the forthcoming discussion. The expiration of the Grandfather Provision applies to two terms used throughout this article: anatomic pathology and technical component.

Pathology is comprised of two primary categories of service, anatomic pathology and clinical pathology. Anatomic pathology is the study of tissues, organs, and specimens obtained during surgery or biopsy. While anatomic pathology has multiple subdisciplines, surgical pathology is the largest. Consequently, hospitals and pathologists sometimes use the terms surgical pathology and anatomic pathology interchangeably. Clinical pathology, the other primary category of pathology service (or clinical laboratory), relates to the study of blood and urine specimens, and is not affected by the expiration of the Grandfather Provision.

The TC of anatomic pathology refers to the preparation of specimens for review by a qualified pathologist. The TC typically involves various procedures to prepare microscope slides, including fixing, embedding, and staining of slides. The study and preparation of the slides is called histology. Thus, the section of the laboratory that prepares the slides may be referred to as the histology laboratory and the qualified staff member is called the histology technician. Once prepared, the slides are reviewed by a qualified pathologist. The review of the slides constitutes the professional component of anatomic pathology, which was not affected by the expiration of the Grandfather Provision.

History of Anatomic Pathology Reimbursement

While some hospitals have outsourced the TC of anatomic pathology for a long time, the proliferation of outsourced arrangements was encouraged by the emergence of prospective reimbursement systems. Prior to 1983, Medicare reimbursed inpatient services at hospitals based on a fee-for-service (FFS) model. FFS models allowed hospitals to be paid for each activity or service performed on behalf of their patients. Medicare changed this model in 1983 when payment for inpatient care was restructured based on a prospective payment system (PPS). Under a PPS, Medicare began to pay hospitals one fixed amount per inpatient hospitalization based on the diagnostic related group (DRG) assigned to each hospitalization. This change altered the financial incentives for hospitals. With payment per hospitalization effectively capped based on the DRG, Medicare’s PPS dissuaded overtesting and encouraged low costs and efficiency.
Following the 1983 restructure, ancillary services for Medicare inpatients, such as radiology and laboratory, were no longer able to function as revenue centers contributing to a hospital’s bottom line. Rather, these departments became cost centers functioning to support the provision of inpatient care. Hospitals were incentivized to reduce costs and forced to consider ways to make their new cost centers more efficient, or consider eliminating them altogether. Over time many other payors followed Medicare’s lead, implementing PPSs of their own based on case-rate or per-diem payments as opposed to the traditional FFS payments. Medicare expanded the prospective payment concept to outpatients in 2000 by implementing the Hospital Outpatient Prospective Payment System (HOPPS). The HOPPS applies ambulatory payment classifications to each outpatient service, similar to the way in which DRGs had been applied to inpatient services since 1983.

The implementation and proliferation of the PPS model brought about a focus on cost reduction, because hospitals were now striving to deliver each episode of care for less cost. Many hospitals identified outsourcing as a potential cost-savings initiative, carefully balancing the opportunity for cost savings with the potential for lost revenue attributable to payors that had not moved to a PPS.

When Medicare initially converted to a PPS for inpatients, independent laboratories were able to bill and collect for anatomic pathology services provided to Medicare inpatients under the Part B fee schedule. As a result, independent laboratories were able to bill and collect for anatomic pathology services performed by independent laboratories on behalf of inpatients and outpatients reimbursed under the PPS. Certain hospitals, many rural and underserved, began outsourcing the TC of anatomic pathology to independent laboratories.

Providers of such outsourcing included independent laboratories that were already providing outreach work. That is, independent laboratories who were providing the TC of anatomic pathology on behalf of local physicians performing biopsies. When certain hospitals moved to outsourcing, these laboratories were able to extend their existing platform to hospital inpatients.

In addition, the relatively low cost of entry into the anatomic pathology laboratory marketplace made it possible for hospital-based pathologists to develop small anatomic pathology laboratories. These laboratories began serving hospital inpatients, sometimes obtaining key resources (e.g., space, equipment) required to deliver these services through financial arrangements with the very hospitals for which they were providing service.

In 1999, Medicare eliminated Part B payment for anatomic pathology services performed by independent laboratories on behalf of inpatients and outpatients reimbursed under the PPS. In doing so, the federal government took the position that Medicare reimbursement for these services was already contained in the PPS reimbursement to hospitals. Under this rationale, continuing to make payment to an independent laboratory would be tantamount to paying twice for the same service. Therefore, hospitals electing to outsource the TC of anatomic pathology were expected to pay the independent laboratories for their services out of their own prospective payment revenues. However, Congress also provided a Grandfather Provision allowing arrangements in place prior to July 22, 1999, to continue. Congress periodically acted to extend the provision several times before ultimately allowing it to expire on June 30, 2012.

**Impact of the Expiration of the Grandfather Provision**

Financial incentives for hospitals and independent laboratories involved in outsourcing arrangements have changed as result of the expiration of the Grandfather Provision. Independent laboratories, no longer able to obtain reimbursement from Medicare for anatomic pathology TC services on behalf of hospital inpatients and outpatients, nevertheless expect payment for these services if they are to continue providing them. Hospitals that must continue to obtain these services for their Medicare patients must evaluate alternatives. Continuing to outsource the TC component of anatomic pathology brings outside expertise and may provide the smoothest transition to the post-Grandfather Provision environment. However, parties who have or will proceed in this manner have many additional considerations as a result of the expiration of the Grandfather Provision.

**Payors and Patients**

The expiration of the Grandfather Provision affected reimbursement to independent laboratories for both Medicare inpatients and outpatients. Generally, no corresponding additional reimbursement is being made available to hospitals in connection with this change. Reimbursement for non-Medicare payors was not directly affected, but may be altered if the insurer opts to follow Medicare’s lead for the structure of such payments. As a result of potential inconsistencies regarding reimbursement depending on payor and patient setting, parties may wish to carve out various aspects of these services and associated payment.

**Compensation Structures**

Various compensation structures are available to govern these relationships prospectively, each with potential benefits and drawbacks.

**Monthly Payment**

Under this structure, a hospital will pay the independent laboratory a fixed amount per month for its anatomic pathology technical work. Their structure allows for ease of compliance and budgeting as the amount is set in advance. Parties may find it challenging to initially agree upon an appropriate value for this payment, especially if the laboratory is unable to isolate the underlying costs associated with servicing the hospital business. Also, this structure may prove inadequate in an environment of material test volume growth or decline.
Payment per Unit

Under this structure, a price list is established typically corresponding to the applicable current procedural terminology (CPT) code for each procedure performed. As this structure is volume driven, it allows for a better relationship between services and payment. Alternative units of measure may include a payment by another unit such as per case or per block. To understand the applicability of these alternatives, it will be helpful to understand that each patient (or case) may have multiple specimens taken, thereby corresponding to multiple CPT codes, and that during processing, each specimen may be cut into one or more blocks. Tracking of volume may present administrative difficulties under non-CPT code-based structures.

Cost plus Pricing

Under this structure, fees are based on the independent laboratory’s actual pass-through costs plus an agreed-upon mark-up. Under this structure an independent laboratory would be required to disclose its costs to provide the services and the parties would need to agree on an appropriate method to allocate cost, making this methodology particularly challenging to implement.

Fair Market Value and Commercial Reasonableness

In the immediate aftermath of the expiration of the Grandfather Provision, the historical level of reimbursement will remain a relevant reference point for independent laboratories. However, hospitals will see this as less relevant given that such reimbursement was not and is not generally accessible for them. While each laboratory may determine the fees charged to a hospital for the TC of anatomic pathology services, there may be Anti-Kickback Statute (AKS) implications if the laboratory were to provide these services to a hospital for no charge or at a price below fair market value (FMV). The Office of Inspector General of the U.S. Department of Health & Human Services has indicated that significant questions are raised under the AKS when a provider furnishes free or reduced-price services to an existing referral source, such as a hospital. The FMV analysis for the technical services must consider the following:

Completeness of the Services

FMV presumes that the independent laboratory is responsible for all of those costs required to deliver the services. An independent laboratory operating within the hospital space may be obtaining certain resources, such as space, equipment, or staff, from the hospital. FMV must assure that all resources are accounted for appropriately. In addition, the parties must assess the commercial reasonableness of arrangements whereby a substantial portion of the services being acquired by hospital are provided using resources owned by the hospital and leased back to the laboratory.

Availability of Market Data

Market-based reimbursement for the TC of anatomic pathology varies widely. Due to the proprietary nature of negotiations, actual reimbursement from commercial insurers is difficult to obtain. Medicare provides widely utilized and publicly available reimbursement data; however, we note significant variance between reimbursement under the physician fee schedule and the HOPPS.

Underlying Costs

Any indication of FMV should consider whether the independent laboratory is covering its costs and earning an appropriate margin for provision of the services. In addition, the application of the cost approach to valuation would suggest including the costs for the hospital to implement a laboratory on its own. Therefore, in reviewing any available market data consideration must also be given to the underlying costs of the technical services.

Insourcing

Operational and physician relationship considerations aside, developing an anatomic pathology laboratory may provide the most favorable financial outcome for certain hospitals. Depending on the size and scope of a hospital’s anatomic pathology program, an anatomic pathology laboratory may be developed in little space with a relatively small capital investment. High-volume laboratories may find that the costs to provide the TC services are lower than the payment required to outsource this service. Further, developing a laboratory will provide a hospital with an opportunity for a revenue stream from outreach work or for work performed on behalf of non-Medicare payors that will pay for this service.

Conclusion

Recent regulatory changes caused by the expiration of the Grandfather Provision have created a need to reexamine existing relationships whereby hospitals secure the TC of anatomic pathology services on behalf of Medicare patients. As additional Part B reimbursement is no longer available, these changes have incentivized hospitals to minimize the costs associated with the TC for anatomic pathology. Some hospitals may elect to develop the ability to provide these services directly (i.e., insource) while others may seek to restructure the existing outsourced arrangement to compensate independent laboratories for providing these TC services. For those hospitals electing to restructure their arrangements, they must consider the patients for which payment is being made, the appropriate payment mechanism, and that the payments are consistent with FMV.

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4 Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2000, Final Rule, 64 Fed. Reg. 211 (Nov. 2, 1999).