
Hospital Outpatient Prospective Payment under Medicare: Background, Overview, and Analysis

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I. Introduction

In August 2000, Medicare outpatient reimbursement underwent substantial change with implementation of the hospital outpatient prospective payment system (OPPS). Replacing the existing fee-for-service paradigm, this system employs a fixed, prospectively determined payment for products and services provided by hospitals in the outpatient setting. Though the OPPS conceptually represents only the latest extension of existing efforts to control healthcare costs through fixed, prospective payments, its direct impact on healthcare institutions and innovation in medical technology via Medicare reimbursement is uncertain. Furthermore, as Medicare's prospective payment systems are frequently adopted by private third-party payers, the new system's effect on the provision of healthcare will likely be felt far beyond Medicare itself. Given this reality, it is crucial that healthcare providers and the medical technology industry fully understand the OPPS and its potential implications.

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II. A Brief History of Prospective Payment

As reimbursement philosophy, the recently implemented OPPTS may be seen as an extension of existing federal efforts to control healthcare costs through prospective payment systems, the best known of which is the Diagnosis Related Group or DRG for hospital inpatient services. Accordingly, it is useful to examine the origins of the DRG and other prospective payment systems in order to better understand the basis for the new system.

A. Background of Prospective Payment Systems Generally

In 1965, Congress enacted legislation establishing the Medicare program.¹ Initially, Medicare retrospectively reimbursed for inpatient and outpatient services based on hospital-specific reasonable costs. Over time, healthcare costs rose substantially, due in part to a surge in the demand for services created by Medicare itself, as well as industry-specific inflation caused by factors such as the cost-based payment methodology, the introduction and availability of new expensive technologies, and the general structure of health insurance plans.² In response, Congress took measures to contain the rising costs of healthcare, the most notable being the introduction of the prospective payment system (PPS).

The prospective payment system was initially implemented in 1983 with passage of section 1886(d) of the Social Security Act, which covered hospital inpatient services.³ This

legislation envisioned establishing cost-effective and efficient healthcare provisions by altering the incentives associated with fee-for-service models. Specifically, the new paradigm shifted financial risk to hospitals, paying only a fixed, prospective payment for inpatient care based on a patient's diagnosis. This meant that costs in excess of the fixed payment were borne by the hospitals themselves, rather than billed to Medicare as part of reasonable costs or charges.

While the PPS model was applied to hospital inpatient services, outpatient services provided by hospitals continued to be paid based on hospital-specific costs. Coupled with a general shift in the site of delivery of medical care from the inpatient to the outpatient setting, this disparate treatment deeply impacted the cost savings envisioned under the PPS.⁴ Despite these problems and occasional Congressional attention, outpatient services continued to be provided on a cost-based payment system for years after the institution of the inpatient system.⁵

The Omnibus Budget Reconciliation Act of 1986 (OBRA) took the first steps in establishing a foundation for a hospital outpatient prospective payment system (OPPS), requiring fiscal intermediaries to use the Health Care Financing Administration Common Procedure Coding System (HCPCS) when reporting hospital claims.⁶ Use of the HCPCS, coupled with a separate provision (section 9343(c)) prohibiting the unbundling of hospital outpatient services, allowed data collection on the types of procedures and services billed by hospitals. Some years

later in 1990, Congress directed HCFA to replace its outpatient fee-for-service payment with a prospective payment fee system.⁷

Five years later, HCFA provided Congress with a report containing gathered data and a proposed structure for a hospital outpatient prospective payment system. This document backed a system based on reimbursement grouped payment by similar services, termed ambulatory patient groups (APGs).⁸ Also in 1995, the agency recommended that Congress correct the error in the blended payment system for ambulatory surgical center, radiology and diagnostic procedures which resulted in Medicare overpayments to providers. Previously, this "blended payment" system assumed that patients paid 20 percent of the Medicare fee schedule amount when they in fact were paying 20 percent of the hospital's billing charges. This resulted in providers receiving more than the fee schedule amount from Medicare, referred to as "formula-driven overpayments."⁹

B. The Balanced Budget Act of 1997

In 1997, Congress enacted the Balanced Budget Act, legislation containing three Medicare-related initiatives designed to ensure budgetary reduction.¹⁰ First, it amended the blended payment system to deduct the actual amount paid by the patient from the fee schedule rate in calculating Medicare's payment amount, effectively eliminating formula-driven overpayments. Second, Congress extended the existing

payment reductions for outpatient operating and capital costs to hospitals through the end of 1999. Lastly, the BBA authorized HCFA to create a prospective payment system for hospital outpatient procedures.

Congress largely accepted HCFA's proposed design of the OPSS in the BBA, providing general system guidelines and leaving operational details to the agency. Specifically, Congress endorsed HCFA's envisioned OPSS structure and granted the agency the authority to group clinically similar outpatient services that used comparable levels of resources into payment groups. HCFA was instructed to calculate initial payment rates and relative weights using a combination of 1996 claims data and the most recent cost report data available. Finally, the statute provided for payment adjustment to reflect regional variations in labor costs.

Congress allowed HCFA, in its discretion, to establish other adjustments, such as increased payments for unusually expensive outlier patients or adjustments for certain classes of hospitals, but did not require them. The statute also froze beneficiary coinsurance at 20 percent of the 1996 national median charges for covered services, as updated to 1999. Congress also required HCFA to establish a procedure where hospitals may elect to reduce the amount of coinsurance for some or all outpatient services.

To begin the implementation process, HCFA published a proposed OPSS rule on September 8, 1998.¹¹ The agency was inundated with over 10,000 comments from various stakeholders, which necessitated the extension of the comment period four times, finally ending

on June 30, 1999. Virtually every aspect of the proposed OPSS was critiqued by some group of providers, industry, beneficiaries, and healthcare associations. Those same groups were simultaneously lobbying Congress to amend the various cost-cutting provisions of the BBA 1997. Delays also resulted from agency preparation for the "millennium bug."

C. The Balanced Budget Refinement Act of 1999

In 1999, Congress enacted numerous modifications to the BBA outpatient payment provisions in the Balanced Budget Refinement Act of 1999 (BBRA) that affected the OPSS.¹² Initially, outlier payment adjustments were made mandatory rather than discretionary, the result of numerous comments questioning HCFA's decision to not create an outlier mechanism in the 1998 proposed OPSS rule.¹³ The agency maintained that the proposed OPSS provided adequate safeguards to equitably cover outlier cases as hospitals could bill for more than one service group a day, unlike the inpatient PPS.¹⁴ However, the BBRA directed HCFA to compensate providers for a portion of the additional costs of care associated with extraordinary patients that exceeded a certain percentage of the normal payment rate.

The BBRA created two other sources of additional payments to hospitals. First, the statute created temporary additional payments to cover the costs of new medical devices, drugs, and biologics.¹⁵ Under the act, these payments are not to exceed 2.5 percent of the total projected outpatient payments until 2004,

and 2 percent for 2005 and beyond. Also, transitional corridor payments are provided to help limit hospital and Community Mental Health Center (CMHC) losses under the OPSS.¹⁶ During 2000 through 2003, providers will receive additional reimbursement if their payment-to-cost ratio for outpatient services during the year is less than a set percentage of their 1996 payment-to-cost ratio for those services.

The BBRA significantly changed another aspect of the proposed OPSS. Originally, HCFA did not include the cost of most implantable devices, such as durable medical equipment (DME) and prosthetics in the procedure group payment amounts. The agency was prevented from including these costs because the DME prospective payment system statute prohibited paying for any DME outside of that fee schedule.¹⁷ However, Congress rectified this situation by allowing payment for certain types of implantable DME and prosthetics under the OPSS.¹⁸

III. Outpatient Prospective Payment System: Structure on Implementation

HCFA published the final OPSS rule, with comment period, on April 7, 2000, with extensive modifications reflecting both the BBRA and stakeholder comments.¹⁹ This rule contained three main parts. One implemented the BBA elimination of "formula-driven" over-payments, while a second detailed the OPSS.²⁰ A final portion contained new "provider-based status" regulations that defined how the agency will treat subordinate facilities of hospitals, such as outpatient departments, for purposes of reimbursement.²¹

The latter provisions formally regulated an aspect of the Medicare program that was previously addressed informally through a 1996 Program Memorandum.²²

A. Qualification for Hospital Outpatient PPS: Provider-Based Status

Under the new policy, hospitals must meet HCFA's "provider-based status" regulations in order to receive payments for outpatient procedures performed in outpatient departments.²³

The regulation's seven criteria are substantially similar to the 1996 Program Memorandum, but there are some important changes.

Initially, a department must operate under the same license as the hospital if permitted to do so under state law. Second, the facility must be wholly owned and fully controlled by the hospital. Joint ventures cannot receive provider-based status as the main provider shares ownership with another party. Third, the department must experience the same administrative requirements and supervisory scrutiny as one of the hospital's traditional departments. The hospital must fully clinically integrate the department, taking such measures as ensuring the department's medical staff has clinical privileges at the hospital, having the same oversight committees control the facility, and integrating medical records, inpatient and outpatient services. Full financial integration of the department into the hospital is also required. Further, the facility should be held out to public as part of the main hospital. Lastly, HCFA shall examine the physical location of the department to

determine provider-based status. The department should either be on or immediately adjacent to the main hospital campus or prove that the department serves substantially the same patient population as the hospital.

Existing outpatient departments must comply with the regulations as of the first date of their cost-reporting period beginning on or after January 10, 2001. HCFA currently does not require existing outpatient departments apply for provider-based status approval nor plan to systematically audit existing outpatient departments, although they reserve the right to conduct such audits should the agency become aware of non-compliance.²⁴ New outpatient departments must receive a favorable agency determination of provider-based status before the hospital can bill Medicare for outpatient services performed at that location.²⁵ Hospitals must also report "any material changes" in relationships with outpatient departments that could affect the status of the department.²⁶

In its accompanying comments, HCFA noted the dramatic changes in the organization of healthcare providers over the past two decades, particularly since the implementation of the inpatient PPS in 1983.²⁷ The emergence of integrated delivery systems and the pressure to enhance revenues have created greater incentives for providers to affiliate and control off-campus treatment settings, such as physician offices. The provider-based status regulations are a response in the form of clear standards to evaluate these arrangements to ensure that true provider-based entities were recognized as such in order to protect patient safety and Medicare funds.

B. Ambulatory Payment Classification Groups

The ambulatory payment classification (APC) system is the heart of the hospital outpatient PPS. Each APC group consists of a cluster of services provided during a particular outpatient procedure. Each service or procedure is identified by its HCFA Common Procedure Coding System (HCPCS) number. Inclusion in an APC group means that services are clinically and resource similar.²⁸ The BBRA imposed a "two-times" requirement in constructing the payment groups so that the highest cost item/service is no more than two times greater than the lowest cost item/service. However, Congress granted HCFA authority to make exceptions in certain circumstances, such as for low volume services.

The initial APC rate was calculated using fiscal year 1999 outpatient claims cost data for each HCPCS code and will be updated annually. HCFA then factors into the rate the costs of other expenses incurred in furnishing the service, such as anesthesia, supplies, recovery and observation rooms and services, intraocular lenses, capital costs and costs to procure donor tissue other than corneal tissue.²⁹ Normally, the cost of drugs and biologics are packaged into the APC as well. However, some new drugs may be eligible for the transitional pass-through payment.

In the proposed OPPTS system, HCFA stated that all costs associated with acquiring donor tissue would be included in the APC rate. The agency received approximately two thousand provider comments urging exclusion of corneal tissue

acquisition costs given the expense of tissue screening and the wide variation in costs throughout the country.³⁰ Subsequently, the agency determined that these issues were best addressed by continuing to reimburse hospitals at reasonable cost for corneal acquisition. Other items not packaged in a procedure's APC group include blood and blood products, casting and splinting, immunosuppressive drugs for organ transplants, and other similarly expensive and infrequently used drugs. Separate APC groups have been created for these items.

While each outpatient procedure group has a single APC rate, this does not translate to equal reimbursement for identical services. Rates are subject to discounting when multiple procedures are performed contemporaneously, with the most expensive APC group paid in full, and all other groups receiving half of their APC rate. Surgical procedures terminated after surgery preparation but before anesthesia will be paid half of the APC payment. Patient coinsurance amounts are to be similarly reduced when multiple surgical procedures are performed. Furthermore, the OPSS takes into account the variance in medical costs between geographic regions and adjusts for wage differences using the inpatient hospital wage index.

C. Type of Covered Services

OPSS regulations give the agency broad latitude to characterize a particular service as appropriate for outpatient care. Certain surgical procedures, radiology (including radiation therapy), clinic visits, partial hospitalization for the

mentally ill, surgical pathology and cancer chemotherapy are listed as types of care that are probably appropriately performed on an outpatient basis.

During the comment period, healthcare providers expressed concern that designating certain procedures as only inpatient services had the potential to limit medical practice, particularly given the rapid advance in medical technology. Comments indicated the belief that physicians and patients should be free to decide whether a procedure should be provided in an inpatient or outpatient setting, based on individual factors. Some commentators stated that it was not only possible to perform procedures formerly considered inpatient services on an outpatient basis, but it occasionally was safer to do so.³¹

The agency acknowledged that while there are unavoidable limitations, it is possible to identify certain procedures as inpatient only for the Medicare population. An invasive procedure that requires at least 24 hours of recovery or observation before the patient can be safely discharged is an example of a procedure that should be performed on an inpatient basis for Medicare patients. Importantly, the agency has been clear that a procedure's placement in the outpatient category does not mandate its performance in that setting, with the final determination dependent on patient-specific factors.

HCFA also maintains that annual OPSS review would provide physicians the opportunity to advocate the reclassification of inpatient services to an outpatient

grouping. In the agency's first annual review, fourteen procedures' designation was changed to allow outpatient performance. A similar re-evaluation was performed prior to promulgation of the final rule, where the agency created outpatient groups for certain procedures formerly considered inpatient only, including surgical laparoscopies, transcatheter therapies, bone marrow transplantation, and the insertion, removal and repair of some pacemakers and defibrillators.

To manage the APC system, HCFA has created an advisory committee.³² The panel members, composed of fifteen representatives of Medicare-participating hospitals, will provide technical and operational guidance to HCFA concerning the clinical and resource similarity of procedures within an APC group and reconfiguring or creating new APCs.

The original OPSS did not include implantable prosthetics and most durable medical equipment (DME) in the fee schedule, as HCFA was required to only reimburse DME under the DME payment system. However, the BBRA contained language advocating payment of certain implantable devices and DME under the OPSS. Accordingly, HCFA's final rule reflected this change. Under these provisions, procedures involving implanted DME and implantable items used in performing diagnostic x-rays and laboratory tests will be packaged into the APC rate for the procedure in which they are employed. In addition, implanted prosthetic devices, excluding dental devices that replace all or part of an internal body organ³³, are reimbursed

under the OPPS.³⁴ Supplies that are currently paid under the DME payment system, such as surgical dressings, will be packaged into the APC rate if used in an outpatient setting.

HCFA excludes services already paid under fee schedules from OPPS reimbursement.³⁵ Accordingly, physician and other healthcare provider costs are not included in the APC rate, and will continue to be reimbursed under the appropriate Medicare fee schedule.³⁶ Non-implantable DME and prosthetics, orthotics, and take-home surgical dressings will continue to be paid under the DME fee schedule.

D. Sources of Additional Reimbursement under the OPPS

As part of the BBRA, Congress created mechanisms to provide hospitals with additional payments during the early years of the OPPS. Initially, the BBRA provides “pass-through” payments for new drugs, devices and biologicals for the first two to three years the product is on the market. In addition, provisions were made for additional payments to compensate for unusually expensive patients or if hospital costs exceeded the APC rate. Finally, HCFA created a special APC group for new technologies that complements the “pass-through” payments.

1. Transitional Pass-Through for Innovative Devices, Drugs or Biologicals³⁷

Given the high cost of new drugs and devices, the BBRA created a special APC group to more accurately reimburse these innovations. Under this system, certain drugs and biologicals are

eligible for “pass-through” payments and assigned to a special APC. Hospitals will ultimately receive 95 percent of eligible drugs’ and biologicals’ average wholesale price and their charge for a device, adjusted to cost.

HCFA has established eight criteria to identify technology eligible for the transitional pass-through system. First, the item must not have been recognized as an outpatient service by HCFA before 1997. Second, the technology must be FDA approved or cleared for use. Third, the use of the technology must be reasonable and necessary for treatment of beneficiary. HCFA recognizes that some devices that have received an investigational device exemption (IDE) from FDA are refinements or replications of existing technologies and therefore may be considered reasonable and necessary. These so-called category B devices are eligible for pass-through payment. Further, HCFA removed the cost limitation³⁸ on reimbursement, and will treat category B IDEs the same as other pass-through devices.

Fourth, the technology must be an integral and subordinate part of the procedure performed. It must also be implanted or inserted in only one patient, come in contact with human tissue and be a single-use device. The device can either remain with the patient after he or she is released from the outpatient department or can be removed during the procedure. HCFA expanded this element in order to include more new devices, such as radiological site clips and tissue markers that are implanted temporarily in a patient. However, HCFA clearly states that single-use

devices must be used only on one patient. Reuse or reprocessing of single-use devices renders the device ineligible for pass-through payment. Accordingly, billing for additional reimbursement for reprocessed or reused single-use devices could constitute Medicare fraud.

Fifth, the associated cost of the technology must meet the definition of “not insignificant” in relation to the APC rate for the service, as explained in the new drug and device criteria. Sixth, no depreciable equipment or instruments are eligible for pass-through payments. A seventh consideration is that materials and supplies, such as sutures, customized surgical kits, or clips, except radiological site markers, may not receive additional reimbursement. Ineligible supplies include pharmacological imaging and stressing agents. Finally, biologicals and synthetics used to replace human skin are excluded from the pass-through program.

Three of the four categories of eligible new technologies for the pass-through APC are relatively straightforward. Provided they meet the eight eligibility criteria, orphan drugs, current cancer therapy drugs, biologicals, and brachytherapy devices and current radio/pharmaceutical drugs and biological products used for diagnostic, monitoring, and therapeutic purposes are eligible for pass-through payments if outpatient payments were made for these items on the first date OPSS is implemented.

New drugs, devices and biologicals were subject to a more complicated set of requirements, until the November 3rd rule simplified the

process. Presently, new drugs and devices can receive pass-through payments if the item was not billable to Medicare before January 1, 1997 and its cost is “not insignificant” in relation to the OPSS fee schedule amount. Until January 1, 2003, “not insignificant” means the technology’s reasonable expected cost exceeds 10 percent of the service’s fee schedule amount. After January 1, 2003, the definition of “not insignificant” contains two additional requirements. First, the expected reasonable cost of the item must exceed the portion of the fee schedule amount that is associated with the item by 25 percent. Second, the difference between the reasonable cost of the item and its portion of the fee schedule must exceed 10 percent of the total fee schedule amount for the service.

This regime represents two important changes from the original “not insignificant” definition. As published in the April rule, beginning at the implementation of the OPSS, pass-through new technologies were required to fulfill all three criteria, and the thresholds for each provision was 25 percent. In the November rule, HCFA restructured the provision as the agency believed that the 25 percent requirement was too severe and could prevent Medicare beneficiaries from accessing the latest technology. Also, it postponed two of the criteria until 2003 in order to better determine the amount attributable to devices, drugs or biologicals in a procedure’s fee schedule.

At the same time HCFA relaxed the pass-through criteria, it acknowledged that currently payments under the program exceed the BBRA limitation of

2.5 percent of OPSS payments. In August, the agency proposed a pro rata reduction in pass-through payments, consistent with this BBRA obligation. However, industry and congressional members objected to the reduction, citing a conflicting promise to not reduce reimbursement rates in 2001. In November 2000, HCFA reversed its position on the reduction, although, the agency warned industry and providers to expect significant reductions in pass-through payments for 2002 in order to fulfill its statutory requirements.

Following publication of the final rule, HCFA has identified several “new technology” devices, including prostatic microwave and RF thermotx and PET for lung imaging and lymphoma staging. As the agency gains information about actual hospital costs incurred in furnishing a new technology service, it will be moved to a clinically related APC group with comparable resource costs or will create a separate APC group for procedures using that device or drug.

One potentially confusing aspect of the transitional pass-through system concerns the actual coverage of the item. HCFA received the following question from a stakeholder: “If an item is on the pass-through list, does it automatically mean that the item is covered by Medicare?”³⁹ HCFA’s answer was somewhat surprising:

No. The pass-through list is only for payment purposes and does not imply a coverage decision. Coverage determinations are made only through HCFA’s National Coverage Decision or by action of a local FI or carrier medical director.

As the OPSS has been only recently implemented, it remains to be seen how this potential conflict will affect its operation.

2. Outliers

In the proposed OPSS, HCFA declined to establish an outlier payment mechanism because it believed that the OPSS sufficiently provided for covering additional expenses incurred for unusual cases.⁴⁰ The BBRA amendments made an outlier system mandatory where costs exceed a fixed percentage of the adjusted APC rate. The regulations state that procedures whose actual costs exceeded 2.5 times the total OPSS payments (APC payment plus any transitional pass-through amounts for drugs, biologicals and or devices) qualify for an outlier payment.⁴¹ In these situations, hospitals will receive 75 percent of the costs that exceed the 2.5 times threshold.

3. Transitional Corridor Payments

The BBRA established a three year “transitional corridor” window until 2003 to ensure that providers do not experience a significant loss in payments under the OPSS.⁴² To implement this provision, HCFA devised a formula to provide additional payments.⁴³ If during 2000-2003 the OPSS payment is less than the payment-to-cost ratio in 1996, calculated as if the formula-driven overpayments had been eliminated, providers will receive a percentage of the difference between the OPSS amount and the hospital’s costs in that year multiplied by the hospital’s 1996 payment to cost ratio. The percentages decrease as the years progress, until phasing out completely in 2004.

There are further targeted transitional payment adjustments. Rural hospitals with 100 or fewer beds and cancer hospitals may have their payments increased to ensure that OPSS payments are not lower than their pre-BBA amount until 2004. HCFA will make additional transitional payments to these providers on an interim basis, subject to retrospective adjustments based on settled cost reports.

4. New Technology APC

In addition to the BBRA measures, HCFA created a special APC group for new technology services or procedures which do not fit into an existing APC group.⁴⁴ These new technology groups are solely based on the cost of the service and do not take into account clinical considerations as do typical APC groups. Services are identified using their Physicians Current Procedural Terminology (CPT) codes and reimbursement rates for these special APC's are based on the average cost of providing the service. As the agency gains data on actual hospital costs, the new technology service will be moved to an appropriate APC group or a new group will be created.

E. Election to Offer Reduced Copayment Amounts

The BBA provides that a hospital's billed copayment must fall between a minimum copayment amount (20 percent of the APC payment rate) and the national copayment amount (based on 20 percent of the wage-neutralized median charges billed in 1996, trended forward to 1999, for each APC group).⁴⁵ As the APC rate

increases and the maximum copayment amount remains fixed, the unadjusted coinsurance amount will eventually become 20 percent of the payment rate for all APC groups. In most instances, HCFA expects the transition to the standard Medicare copayment rate will be gradual. For those APC groups that still experience a copayment that is a relatively high proportion of the total payment, the adjustment process will be correspondingly lengthy. Accordingly, the BBA and the OPSS provide hospitals the option of electing to reduce copayment amounts to not less than 20% of the APC rate and permit the hospitals to disseminate information on their reduced rates to the public.⁴⁶

Hospitals, prior to the start of a payment year, may elect to reduce the copayment amount otherwise established for some or all hospital outpatient services. Providers must notify their fiscal intermediary in writing of their election to reduce copayments no later than 30 days prior to the start of that year. The notification must specifically identify the APC groups which the provider has decided to reduce and the copayment level that the provider has selected for each group. The election of reduced copayment must remain in effect and unchanged during the year for which the election is made. Providers may not elect to reduce the copayment amount for some, but not all, services within the same APC group.

In determining whether to make an election, HCFA advises hospitals to note that the national copayment amount under the OPSS, based on 20 percent of national median charges for each APC, may yield copayment amounts that

are significantly higher or lower than the copayment that the provider previously has collected. This is because the median of the national charges for an APC group, from which the copayment amount is ultimately derived, may be higher or lower than the provider's historic charges. No reduction in copayments elected by the hospital may be treated as bad debts.

IV. OPSS Impact

While prospective payment systems in American medicine are not novel, their application to the hospital outpatient setting under the Medicare program is a decidedly new application. Initially, the actual operation of the new system and its direct financial impact on healthcare institutions have yet to be fully developed and understood. Perhaps as importantly, its impact on the introduction of new medical technology in the outpatient setting, where much innovation is currently focused, is unclear.

HCFA itself, in a regulatory analysis, has generated an estimate as to how the new system will affect hospital payments both with and without the transitional corridors payments.⁴⁷ Excluding transitional payments, HCFA estimates that total outpatient payments to all hospitals will increase 0.2 percent under the OPSS and total Medicare payments will not increase at all. Children's hospitals stand to lose the most under the system, receiving 11.9 percent less in outpatient payments and 2 percent less in Medicare payments. Psychiatric hospitals are posed to benefit the most, increasing their outpatient payments by 21.3 percent and Medicare payments by 1.9 percent. Major teaching

hospitals are estimated to lose 3.7 percent of outpatient revenue resulting in a 0.3 percent Medicare reduction. Rural hospitals will also lose 0.3 percent of their Medicare payments with a 1.8 percent reduction in outpatient reimbursement. Urban hospitals are expected to slightly increase their outpatient and Medicare payments by 0.6 and 0.1 percent respectively.

However, when HCFA factors in the additional funds available through transitional payment mechanisms, only children's hospitals continue to lose Medicare dollars, and only by 0.5 percent because of a 3.2 percent reduction in outpatient payments. All other types of hospitals would receive an average of 4.6 percent more in outpatient payments, resulting in a 0.5 percent increase in Medicare money received than before the OPSS was implemented.

The OPSS has not been in place long enough to access whether these estimates are correct. In an effort to obtain preliminary data, the American Hospital Association surveyed 551 hospitals concerning the effects of the OPSS. Since the system was implemented August 1, 2000, over 23 percent of these hospitals reported hiring additional staff to process outpatient claims.⁴⁸ As compared to claims submitted during September 11-17, 1999, almost sixty-seven percent of these hospitals received less than that received for comparable claims submitted during that week in 2000. The AHA plans to follow this initial survey with a more detailed study of the OPSS impact.

Aside from the new system's direct financial effect on

hospitals, there is the question of its disproportionate application and how that asymmetry will affect where and how healthcare is delivered. Specifically, the OPSS applies only to hospital outpatient settings, not non-hospital affiliated outpatient facilities. It is likely that this asymmetric application will result in a disruption of the pre-OPSS financial equilibrium, resulting in a financial advantage to either hospital-affiliated or non-hospital affiliated outpatient care, with the potential to affect the setting where that care is delivered.

Through its application and specific APCs, the OPSS has potential to impact medical practice as well. For example, several physicians groups have expressed concern that HCFA's packaging of observation care within an APC will result in a disincentive to provide this valuable clinical service.⁴⁹ More generally, it is likely that the complex new system will create unintended financial incentives and disincentives to provide particular medical products and services.

The system's sheer complexity is another area of concern. Depending on the product or service provided, funds can come from several distinct provisions of the OPSS, making accurate hospital accounting difficult and possibly costly. This complexity may also result in hospital outpatient billing errors that could result in over- or underpayment. In particular, the former is potentially problematic, as systematic overpayment could be used by HCFA to support allegations of Medicare fraud.

Perhaps the area of greatest concern is the ultimate impact of the OPSS on Medicare patients,

particularly the development of and access to innovative technologies that have had such a positive impact on health and quality of life of the elderly and disabled. If the new system removes industry's incentive to innovate and providers ability to provide innovative, new technology, it is possible that Medicare beneficiaries will not share in broader medical advances, or that those advances will simply not occur.

Regardless of these and other concerns, there is little doubt that the OPSS is destined to be a long-standing, if not permanent, addition to reimbursement under the Medicare program. As such, it will have a defined impact on hospitals as well as those who develop and market new medical technologies, and possibly on Medicare beneficiaries themselves. However, given the magnitude of the change and the complexity of the system, it will likely be years before its true effect may be accurately gauged. Though this uncertainty may be unsettling, it is important to note that HCFA has demonstrated a willingness to work with the stakeholder community to reach workable solutions to OPSS issues recognized to date. It is incumbent on the stakeholder community to be vigilant in its assessment of OPSS impact, and to move together with HCFA to productively address issues as they arise.

References

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² Judith R. Lave, *The Impact of the Medicare Prospective Payment System and Recommendations for Change*, 7 Yale J. on Reg. 499, 502-503 (1990).

³ Social Security Amendments of 1983, Pub. L. No. 98-21, § 601, 97 Stat. 65 (1983)(codified as amended at 42 U.S.C. 1395ww (1982 & Supp. 1987)).

⁴ Office of Inspector General; Medicare Program; Prospective Payment System for Hospital Outpatient Services, 65 Fed. Reg. 18434, 18436 (2000) (to be codified in scattered sections of 42 C.F.R.).

⁵ As control measures, Congress implemented across-the-board reductions of 5.8 percent in operating costs and 10 percent in capital costs in amounts payable by Medicare. In addition, Congress enacted various payment methods including fee-schedules, composite rate payments, and blended payments. See, *Id.*

⁶ Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9343(g), 42 U.S.C. 1395ll (1986).

⁷ See Prospective Payment System for Hospital Outpatient Services, 65 Fed. Reg. 18434, 18436 (2000).

⁸ See *id.*

⁹ See *id.* at 18437.

¹⁰ See *id.* at 18437-38.

¹¹ See *id.* at 18438.

¹² See *id.* at 18438-39.

¹³ See *id.* at 18497.

¹⁴ See *id.* at 18497.

¹⁵ See *id.* at 18439.

¹⁶ See *id.* at 18439.

¹⁷ See *id.* at 18443.

¹⁸ See *id.* at 18439.

¹⁹ Various provisions of the final rule have been amended in the August 3 Federal Register notice.

²⁰ See 42 C.F.R. § 413.118 (2000).

²¹ See 42 C.F.R. § 413.65 (2000).

²² See Medicare Program Memorandum, A-96-7.

²³ A provider “department” is defined as a facility, organization or physician office either created or acquired by the hospital for the purpose of providing healthcare services that are of the same type as those provided by the hospital under the name, ownership, and financial and administrative control of the hospital. 42 C.F.R. § 413.65(a)(2).

²⁴ 65 Fed. Reg. at 18508.

²⁵ 42 C.F.R. § 413.65(b)(2000).

²⁶ 42 C.F.R. § 413.65(c)(2000).

²⁷ See 65 Fed. Reg. at 18504.

²⁸ See 42 C.F.R. § 419.31.

²⁹ See 42 C.F.R. § 419.2(b)(2000).

³⁰ See 65 Fed. Reg. at 18449.

³¹ See 65 Fed. Reg. at 18455-56.

³² See HCFA Press Office, *Advisory Panel On Ambulatory Payment Classification Groups Established*, HCFA Fact Sheet, Dec. 5, 2000.

³³ This includes colostomy bags and supplies.

³⁴ See 42 C.F.R. § 419.2.

³⁵ Screening mammographies, services to ESRD patients paid under the ESRD composite rate and laboratory services paid under the clinical diagnostic laboratory fee schedule are also excluded for the OPPTS.

³⁶ See 42 C.F.R. § 419.22.

³⁷ See 42 C.F.R. § 419.43(e); 65 Fed. Reg. at 18476-82.

³⁸ See 42 C.F.R. § 405.209.

This regulation bases reimbursement for Category B investigational devices on, and may not exceed, the amount that would have been paid for a

currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA.

³⁹ Medicare Learning Network Q&As PASS-THROUGH DEVICES, available at <http://www.hcfa.gov/medlearn/devicqa.htm> question posed (09/12/00).

⁴⁰ See 65 Fed. Reg. at 18497-99.

⁴¹ See 42 C.F.R. § 419.43(d).

⁴² See 65 Fed. Reg. at 18499-500.

⁴³ See 42 C.F.R. § 419.70.

⁴⁴ See 65 Fed. Reg. at 18476-78.

⁴⁵ See 65 Fed. Reg. at 18493.

⁴⁶ See 42 C.F.R. § 419.42.

⁴⁷ See 65 Fed. Reg. at 18533-34.

⁴⁸ *Hospitals Report Increased Staffing, Less Payback In Wake of OPPTS Launch*, AHA News, October 2, 2000, at <http://www.aha.org>.

⁴⁹ Jane Cys, *Physicians Worry That HCFA Payment Decision Will Hurt Care*, American Medical News, November 27, 2000, at

<http://www.ama.org/sci-pubs/amnews>.