Chapter 39

Drug, Device, and High-Tech Suppliers: Environment in an Era of Cost Containment

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I. INTRODUCTION

§ 39:1 Generally

The legal environment governing healthcare providers has a tremendous impact on the types of items and services providers furnish, and thus can greatly affect the market for new medical technology. This is evident from an examination of the coverage and payment rules relating to hospitals and physicians under Medicare.

Historically, Medicare paid physicians and hospitals for inpatient and outpatient services through rather generous reimbursement systems, based primarily on charges or costs. These payment methodologies facilitated the diffusion of breakthrough drugs, biologicals, devices, and procedures. Hospitals and physicians used these new technologies — often regardless of cost — whenever such technology promised some potential clinical benefit to their patients.

In later years, however, policymakers — concerned about ever-increasing healthcare costs — have implemented a number of coverage and reimbursement changes that drastically has affected the willingness of hospitals and physicians to adopt new technology, particularly cost-increasing technology for which the quality of life benefits are difficult to quantify. This section will examine some of these changes with respect to their impact on drugs, biologicals, devices, and procedures furnished by physicians and hospitals. This section will not address other legal issues which, despite the fact that they may have significant impact on medical technology manufacturers, are beyond the scope of this Practice Guide. These include, for example, changes in the law in the areas of the Food and Drug Administration ("FDA"), product liability, and patents.

II. MEDICARE COVERAGE

§ 39:2 Generally

Medicare covers items and services that fit into broadly defined benefit categories such as physician services, hospital services, durable medical equipment, or diagnostic services. In addition, the statute limits coverage by excluding payments for items and services which are "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[1] This broad language vests significant discretion in the Centers for Medicare & Medicaid Services ("CMS") and its contractors to determine what is and is not covered. These decisions are made nationally by CMS and locally by Medicare contractors.

§ 39:3 — National Coverage Decisions

CMS makes national coverage decisions for some items and services, and the decisions are binding on all Medicare contractors.

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[1] 42 U.S.C.A. § 1395y(a)(1)(A).

Currently, national coverage decisions are made by CMS on approximately ten percent of the new items or services.[1] In response to criticism about the uncertain criteria used to make the decisions, CMS revised the national coverage process in 1999 to make it more open and transparent. The process can be initiated by CMS or by an outside request, but CMS will generally only initiate the process when its contractors have conflicting policies, the service represents a significant benefit or detriment to Medicare beneficiaries, or the service is subject to substantial controversy.[2]

During the evaluation process CMS considers a number of factors in evaluating items and services for coverage using both internal and external resources. The agency reviews any scientific information available such as clinical trials, published case studies, the FDA status of approval and indications, and more.[3] However, if the issues concerning the coverage of a specific item or service are medically or scientifically complex, controversial, or involve broad health policy concerns, CMS can refer the issue for a technology assessment or to the Medicare Coverage Advisory Committee ("MCAC").

The MCAC is comprised of a maximum of one hundred members selected by the Secretary of Health and Human Services. It reviews the medical literature and examines data on effectiveness and appropriateness of medical services. The MCAC meets six to ten times per year and the meetings are open to the public, unless the Secretary determines otherwise.[4]

CMS also can seek a technology assessment to assist in making a coverage determination. CMS often uses the Agency for Healthcare Research and Quality ("AHRQ") for technology assessments. After considering the result of the MCAC review or technology assessment, CMS will then issue a decision memorandum.

The decision memorandum serves as the announcement of the agency's intention to make a national coverage decision.[5] It explains the reasons for the decision, addresses the evidence presented, and may include the recommendations of the technology assessment of

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[1] *See* John Whyte, *Medicare Coverage policies made easy: How decisions are made*, HealthLeaders, Jan. 4, 2002, available at *http://www.healthleaders.com/news/feature1.php?contentid=30579*.

[2] 64 Fed. Reg. 22,619, 22,621 (April 27, 1999).

[3] 64 Fed. Reg. 22,619, 22,621–2 (April 27, 1999).

[4] MCAC Charter (Nov. 22, 2002), at *http://www.cms.hhs.gov/mcac/8b1–l.asp*.

[5] 64 Fed. Reg. 22,619, 22,624 (April 27, 1999).

the MCAC.[6] The decision memorandum is not binding upon Medicare contractors until further instructions are issued by CMS.[7] A decision memorandum will contain one of the following determinations:national coverage without limitations; national coverage with limitations; national noncoverage; or no national determination, with coverage left to the discretion of the contractors.[8] According to CMS, the decision memorandum should be issued within ninety days of receiving a formal request or sixty days after receipt of the technology assessment or MCAC recommendation, and will be placed on its web-site.[9] Within sixty days of posting the decision memorandum, CMS is supposed to issue the national coverage determination.[10]

In December of 2000, Congress revised the Medicare coverage process to require CMS to ensure that the public has an opportunity to comment on a national coverage determination prior to the implementation of the decision.[11] In addition, Congress required that the national coverage determination provide a clear statement for the basis of the determination including responses to comments, the assumptions underlying the determination, and that CMS make available any non-proprietary data used in the determination.[12] However, CMS has not taken specific steps in response to these statutory changes.

In BIPA, Congress made another significant change regarding Medicare coverage decisions. Until recently there was limited administrative or judicial review of these decisions. However, Congress revised the Medicare statue to allow for appeals of national

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[6] 64 Fed. Reg. 22,619, 22,624 (April 27, 1999).

[7] 64 Fed. Reg. 22,619, 22,624 (April 27, 1999).

[8] 64 Fed. Reg. 22,619, 22,623 (April 27, 1999).

[9] 64 Fed. Reg. 22,619, 22,624 (April 27, 1999). A list of Medicare national coverage decisions is available at *http://www.cms.hhs.gov/ncd/ncdindexlist.asp*.

[10] 64 Fed. Reg. 22,619, 22,624 (April 27, 1999). According to CMS this delay is necessary to determine how the item or service should be coded and paid, and so that the necessary claims processing instructions can be issued. *See id*.

[11] 42 U.S.C.A. § 1395y(a) (as amended by § 522(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106–554 ("BIPA")).

[12] 42 U.S.C.A. § 1395y(a) (as amended by § 522(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106–554 ("BIPA")).

coverage decisions to the Departmental Appeals Board ("DAB") within HHS, with the DAB's decision subject to judicial review.[13] Although Congress directed CMS to make such review available as of October 1, 2001, CMS decided to undertake notice and comment rulemaking before doing so.[14]

As a result of these recent changes, the national coverage decisionmaking process has become more open, with greater contribution coming from sources outside CMS, like the MCAC. However, the ultimate decisions are made by CMS and the agency has resisted external checks on its decisionmaking (*e.g.*, public comments before decisions are final and appeals of decisions). It is not clear if the increased openness prolongs national coverage decisionmaking, although the external checks when implemented could have such an effect.

§ 39:4 — Local Coverage Decisions

The most frequently utilized method for making Medicare coverage decisions is through the Medicare contractors. In the absence of a binding national coverage decision, Medicare contractors have discretion to cover new technologies within the statutory parameters.[1] The local coverage decisionmaking gives new technologies the opportunity to diffuse into use throughout the country so that physicians and other healthcare providers can gain real-world experience with the technologies. Local coverage decisions also take into account local variations in accepted medical practice, although the result can be conflicting coverage decisions among geographic areas. The contractor coverage decisions can be made through the processing of an individual claim or the establishment of a local medical review policy ("LMRP").

Historically, the issuance of LMRPs and the standards used in developing them were unstated and seemed to be applied haphazardly. In November 2000, CMS directed Medicare contractors to develop and publish LMRPs through a process similar to notice and

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[13] 42 U.S.C.A. § 1395ff(f)(1) (as amended by § 521 of BIPA).

[14] CMS Ruling 01–01 (Sept. 28, 2001), available at *http://www.cms.gov/rulings/01–01.asp*. The proposed rule was issued on August 22, 2002. 67 Fed. Reg. 54,534.

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[1] 64 Fed. Reg. 22,619, 22,621 (April 27, 1999).

comment rulemaking.[2] In the course of establishing an LMRP, the contractor must allow interested parties to submit information, conduct open meetings for discussing the proposals, post draft LMRPs on its website, solicit comments and summarize the comments received. Final LMRPs must be posted on the contractor's website.[3]

Congress recently amended the Medicare statute to set forth a mechanism for appeals for LMRPs that is similar to the mechanism for appealing national coverage decisions.[4] Aggrieved parties may bring an appeal to an administrative law judge ("ALJ"), who can review and overturn a contractor's LMRP.[5] The ALJ's decision is reviewable by the DAB and the DAB's decision, or the ALJ's decision if the DAB does not review the case, is subject to judicial review. As noted above, CMS will undergo notice and comment rulemaking before implementing this appeals mechanism and has issued a proposed rule.

The more open and predictable local coverage decisionmaking process should prove to be beneficial for coverage of new technologies. Proponents of new technologies should have a better understanding of how to navigate the local coverage process. Once the BIPA appeal mechanism for LMRPs is implemented, providers should be able to obtain a more prompt and unbiased review of an LMRP.

III. NEW TECHNOLOGY FOR HOSPITAL INPATIENTS

§ 39:5 Generally

Since the advent of the prospective payment system for inpatient hospital services ("Inpatient PPS") in 1983, hospitals paid under this system have been provided little financial incentive to utilize new technologies unless they are less expensive than existing technolo-

[2] Program Memorandum AB-00–116 (Nov. 24, 2000) available at *http://www.cms.hhs.gov/manuals/pm_trans/AB00116.pdf*; 64 Fed. Reg. 22,619, 22,621 (April 27, 1999).

[3] Program Memorandum AB-00–116 (Nov. 24, 2000) available at *http://www.cms.hhs.gov/manuals/pm_trans/AB00116.pdf*; 64 Fed. Reg. 22,619, 22,621 (April 27, 1999).

[4] 42 U.S.C.A. § 1395ff(f)(2) (as amended by § 522 of BIPA). Local coverage decisions have been appealable through the Part A or Part B claims appeals process. These processes require a few levels of review by the contractor of its own LMRP. Rarely have the contractor reviewers failed to follow an LMRP.

[5] 64 Fed. Reg. 22,619, 22,621 (April 27, 1999).

gies or can otherwise reduce the hospital's costs for treating patients, e.g., by reducing length of stay. Medicare's diagnosis related group ("DRG") system generally pays each hospital a fixed amount for an admission, regardless of the specific items or services (or new technologies) furnished by the hospital based on the patient's diagnosis.[1]

Over the years, CMS has utilized this system to slow the proliferation of new technology and has done so intentionally, believing that Medicare should not immediately recognize the additional costs for new technologies.[2] Historically, in order to increase Medicare reimbursement for cases using a new technology under Inpatient PPS, these cases must be reclassified to a higher paying DRG or moved to a new DRG. This, however, is a lengthy process.

First, an International Classification of Diseases, Ninth Revision ("ICD-9") code for the new technology must be assigned so that CMS can track the costs of those cases using the technology. In general, new technology may not be assigned an ICD-9 code until it has received FDA approval. In the past, it has taken as little as one year and as long as two years or more to obtain an ICD-9 code. CMS only added new codes once each year — effective October 1. The committee that assigns codes (the ICD-9 Coordination and Maintenance Committee [the Committee]) met in May or June and November or December of each year. Codes approved based on either meeting were not effective until October 1 of the following calendar year. Pursuant to a recently revised process, the Committee's spring meeting is conducted a month earlier and approved codes from that meeting may be effective on October 1 of the same calendar year.[3] With requests for consideration of a code due a few months prior to the Committee meeting, under this revised process, an ICD-9 code could become effective in as little as 6 months after a request for a code is submitted, although it could still take up to 17 months to get a code.

After undergoing the lengthy process to obtain an effective ICD-9 code, additional delay results from CMS's policy of waiting until it collects at least a year of Medicare Provider Analysis and Review ("MedPAR") data regarding the ICD-9 code before the agency will assess whether cases using the new technology should be reclassified

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[1] *See* Chapter 16 for a more complete description of Inpatient PPS.

[2] 66 Fed. Reg. 22,646, 22,695–96 (May 4, 2001).

[3] 66 Fed. Reg. 46,902, 46,906 (Sept. 7, 2001). No change was made to the effective date for codes considered at the November/December meeting.

to a different or a new DRG. At its quickest, this process would take an additional two years, meaning that CMS would not move cases utilizing a new technology to a higher paying DRG until, at a minimum, two and a half years had passed since FDA approval.

During this time, proponents of new technologies that increase a hospital's cost of treating patients in a given DRG face an uphill battle in convincing hospitals to utilize the technologies. Such technologies present hospitals with additional costs they may not be able to recover. If, however, the new technologies are less costly to the hospital than existing technologies that are used, or if use of the new technology otherwise lowers hospitals' treatment costs, hospitals would have an incentive to utilize the technology. CMS believes that a few years time lag before a DRG change is made for a new technology is appropriate because it allows the agency to obtain accurate price, cost, and utilization data.

As an illustration of this principle, CMS points to a situation in the 1980's in which it refused to establish a payment adjustment for a certain costly drug under the DRGs because the usual adjustments would adequately compensate the hospitals. In practice, CMS found that the drug lowered the hospitals' treatment costs because the average length of stay for patients receiving the drug fell. In addition, use of the drug was not as widespread as projected. Thus, concluded CMS, "[e]stablishing an add-on payment for this drug might have actually led to more extensive use of this drug for patients who would not have benefited, and might have even been harmed."[4] Experiences such as this cause CMS to believe that an immediate DRG change for new technologies is not always appropriate.

With CMS unwilling to expedite the timing for DRG changes for new technologies on its own, efforts were undertaken to require CMS to act more expeditiously. In the Conference Report to the Balanced Budget Act of 1997, Congress urged CMS to accept non-MedPAR data and use such data to make DRG changes. Congress believed that acceptance of non-MedPAR data would expedite DRG changes for cases utilizing new technology.[5] In response to this statement by Congress, CMS set forth a process pursuant to which it would accept non-MedPAR data. The data would have to be submitted by December 1 each year, and they would have to be specific enough to allow

[4] 66 Fed. Reg. 22,646, 22,695–96 (May 4, 2001).

[5] H.R. Conf. No. 105–217, 734 (1997).

CMS to identify the beneficiaries receiving the treatment. CMS also indicated that data on all cases within the DRG utilizing the new technology would have to be submitted for CMS to make a DRG change.[6] These requirements effectively make it very difficult to utilize non-MedPAR data to bring about a DRG change.

Congress again addressed the issue of payment for new technologies under Inpatient PPS in BIPA. Section 531 of BIPA amended the Inpatient PPS statute to require CMS to develop a mechanism for recognizing the costs of new medical services and technologies under Inpatient PPS. According to the statute, this mechanism is to apply to services and technologies if the applicable DRG payment rate is inadequate.[7] For a "qualifying" service or technology, CMS is supposed to collect data on it and make a payment "that adequately reflects the estimated average cost of such service or technology," for two to three years, after which cases using the service or technology will be classified into a new or existing DRG.[8] The statute leaves CMS with significant discretion to determine how to make the additional payment, allowing it to be done through a new technology group, an add-on payment, or other mechanism.[9] Finally, the statute requires CMS to establish criteria for determining whether a medical advance can be considered a "new medical service or technology."[10]

CMS implemented this provision through notice and comment rulemaking.[11] Addressing the statutory mandate to recognize costs of new technology, CMS requires that a service or technology satisfy the following three criteria to be eligible for additional payments:

1. It must represent an advance that substantially improves the diagnosis or treatment of Medicare beneficiaries, when compared to previously available technologies. CMS will utilize a panel comprised of CMS clinical staff that may be supplemented with outside expertise as necessary. The panel will look at the following to determine if a new technology represents a substantial improvement:

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[6] 64 Fed. Reg. 41,490, 41,500 (July 30, 1999).

[7] 42 U.S.C.A. § 1395ww(d)(5)(K)(ii)(I).

[8] 42 U.S.C.A. § 1395ww(d)(5)(K)(ii)(II)–(IV).

[9] 42 U.S.C.A. § 1395ww(d)(5)(K)(v).

[10] 42 U.S.C.A. § 1395ww(d)(5)(K)(vi).

[11] 66 Fed. Reg. 22,646 (May 4, 2001) (proposed rule); 66 Fed. Reg. 46,902 (Sept. 7, 2001) (final rule).

- The technology offers a treatment option for patients unresponsive to, or ineligible for, other available treatments;
- The technology offers the ability to diagnose a condition that is now undetectable, or it permits earlier diagnosis of a condition (with evidence that earlier detection affects the management of the patient);
- The technology results in a significant improvement in outcomes evidenced by:
    - Reduced mortality;
    - Reduced complications;
    - Reduced need for subsequent diagnostic or therapeutic interventions;
    - Reduced future hospitalizations or physician visits;
    - Quicker resolutions to the medical ailment;
    - Reduced pain or other symptoms; and
    - Reduced recovery time.

2. The technology also must be considered "new." A technology will be considered to be "new" for 2–3 years beginning when data become available reflecting the ICD-9 code assigned to the new technology.
3. The applicable Inpatient PPS rate must be found to be inadequate. The charges of cases using the new technology must exceed one standard deviation beyond the mean standardized charges for all cases in the applicable DRG.[12] On average, the charges for cases must be about 50% of the DRG payment amount to meet this threshold. For a new technology utilized in cases that may fall in different DRGs, CMS will evaluate the adequacy of payments across all DRGs and the new technology will qualify for additional payments for cases in all DRGs or in no DRGs.[13]

[12] In the final rule, CMS decided to use a standard deviation based on logarithmic distribution, which reduces the standard deviation for each DRG compared to the standard deviations the agency had proposed. 66 Fed. Reg. 46,902, 46,917 (Sept. 7, 2001).

[13] 66 Fed. Reg. 46,902, 46,918 (Sept. 7, 2001). CMS recently proposed reducing the charge threshold to 75 percent of one standard deviation beyond the mean standardized charges. 68 Fed. Reg. 27,154, 27,189 (May 19, 2003).

These criteria appear difficult to meet and to reflect a continuing reluctance by CMS to provide hospitals with any financial incentive to utilize new technologies.

This reluctance is also apparent in the amount of additional payment for new technologies meeting the above criteria. For such cases, CMS will pay an amount in addition to the applicable DRG payment. The additional payment is the lesser of 50% of the estimated cost of the new technology or 50% of the difference between cost of the case and the DRG payment, determined on a case-by-case basis. However, the additional payment will be made only if the cost of the case in which the new technology is utilized exceeds the applicable DRG payment. For example, if the DRG payment for a case in which a new technology is utilized is greater than the hospital's costs (based on charges adjusted to cost) for that case, no payment above the DRG payment will be made.[14]

Because of a budget neutrality requirement, CMS's estimate of payments for new technologies will cause a reduction in other Inpatient PPS payments. CMS established a target limit for new technology payments of 1% of total operating prospective payments. If the agency estimates that new technology payments will exceed the target limit, it will lower the marginal payments for new technologies. Additional payments first will be made for discharges occurring on or after October 1, 2002. Despite legislative intervention, the prospect for prompt recognition of the costs for new technologies under Inpatient PPS remains dim.

[14] To illustrate the payment mechanism for new technologies (assuming the target limit will not be exceeded), assume that a DRG pays $10,000 and a new technology estimated to cost $2,000 is utilized. The maximum additional payment a hospital could receive for the new technology would be $1,000. However, if a hospital's charges adjusted to cost were $7,000 for a case in which the new technology was used, the hospital would receive the $10,000 DRG payment, but no additional payment for the new technology (because the hospital's costs for the case plus the cost of the new technology is less than the DRG payment). If a hospital's charges adjusted to cost for a similar case were $10,500, the hospital would be paid the $10,000 DRG payment plus an additional $250 for the new technology (50% of the difference between the cost and the DRG payment). In all cases in which the hospital's charges adjusted to cost equal or exceed $12,000, the hospital would receive the $10,000 DRG payment plus an additional $1,000 for the new technology.

IV. NEW TECHNOLOGY FOR HOSPITAL OUTPATIENTS

§ 39:6 Generally

On August 1, 2000, Medicare commenced paying for hospital outpatient services under the Outpatient Prospective Payment System ("Outpatient PPS"), which is similar, but not identical, to the DRG system for inpatient services. Prior to that, hospitals were reimbursed for new technology provided to outpatients on a reasonable cost basis. Even if specific codes did not exist for a new technology, hospitals still could obtain reimbursement immediately from Medicare based on its charges for the new technology, adjusted by hospital specific cost to charge ratios.

Under Outpatient PPS, hospitals now are paid a fixed, pre-determined payment amount for outpatient items or services, as they have been since 1984 for inpatient services. Items and services are grouped into ambulatory payment classifications ("APCs") based on the applicable Current Procedural Terminology ("CPT") or Healthcare Common Procedure Coding System ("HCPCS") code. Each APC is assigned a fixed, pre-determined payment rate on an annual basis. Contrary to the DRG system, multiple APCs may be billed for each outpatient encounter to describe the various outpatient services that might be provided.

When CMS first proposed the prospective payment system for hospital outpatient services, CMS provided no mechanism to account for the costs of new technologies.[1] Subsequent to the proposed rule, Congress enacted legislation requiring CMS to make additional, "pass-through" payments for four categories of products: (i) current orphan drugs and biologicals; (ii) current cancer therapy drugs and biologicals and devices of brachytherapy; (iii) current radiopharmaceutical drugs and biologicals, and (iv) "new" medical devices, drugs and biologicals.[2] The statute requires CMS to make additional payments for qualifying pass-through items for a 2–3 year period, during which time, CMS can collect data to incorporate the

[Section 39:6]

[1] 63 Fed. Reg. 47,552 (Sept. 8, 1998).

[2] 42 U.S.C.A. § 1395l(t)(6)(A). Initially, for a drug, biological, or device to qualify under the "new" category, the product must not have been paid as an outpatient service prior to 1997 and its cost must have been not insignificant in relation to the Outpatient PPS payment amount. 42 U.S.C.A. § 1395l(t)(6)(A)(iv).

item into the APCs.[3] Pass-through drugs and biologicals are paid at 95% of average wholesale price, and pass-through devices are paid at the hospital's charge for the device adjusted to cost.[4] Congress imposed limits on pass-through payments that CMS could make during a calendar year and instructed CMS to reduce payments for pass-through items if the agency estimates that pass-through payments in the year will exceed the limit.[5]

CMS also recognized that its proposal regarding implementation of Outpatient PPS failed to account for the costs of new technologies, so the agency developed an administrative mechanism to make additional payments for new technologies. CMS considers a service to be a "new technology" if it: (1) does not qualify as a transitional pass-through; (2) could not have been adequately represented in the claims data being used for the current payment rates; (3) cannot reasonably be placed in an existing APC; (4) falls within the scope of Medicare benefits; and (5) is determined to be reasonable and necessary.[6]

In the 2003 Outpatient PPS rulemaking, however, CMS took other actions that lessened payments for new drugs and biologicals. The agency determined that one product that had continued pass-through eligibility (darbepoetin alfa) and one product that did not as of 2003 (epoetin alfa) were "functionally equivalent" and thus the agency would make equal payments for the products at the lower rate. According to CMS, two products are functionally equivalent if they "use the same biological mechanism to produce the same clinical result."[7] In effect, CMS applied the functionally equivalent standard to cut short the two to three year pass-through period for a new product. Similarly, the agency determined that new radiopharmaceutical products will not be eligible for pass-through payments because such products are not considered "drugs" or "biologicals" under Medicare (despite the fact that the FDA approves them as such).[8] Thus, CMS seems intent to curtail additional payments for new drugs and biologicals to the extent feasible.

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[3] 42 U.S.C.A. § 1395l(t)(6)(C).

[4] 42 U.S.C.A. § 1395l(t)(6)(D).

[5] 42 U.S.C.A. § 1395l(t)(6)(E). Through calendar year 2003, the limit on pass-through payments is 2.5% of total outpatient payments, and is up to 2% thereafter.

[6] 66 Fed. Reg. 59,856, 59,900 (Nov. 30, 2001).

[7] 67 Fed. Reg. 66,718, 66,758 (Nov. 1, 2002).

[8] 67 Fed. Reg. 66,718, 66,757 (Nov. 1, 2002).

CMS places a service that qualifies as a new technology into a new technology APC. These APCs are unique in that items are grouped into these APCs solely based on their costs without regard to clinical considerations. Thus, a service's cost will determine into which new technology APC it will be placed. The service will remain payable under a new technology APC until CMS assembles sufficient information about actual hospital costs so that it can incorporate the new technology into an appropriate APC.[9]

When CMS first implemented Outpatient PPS, these two mechanisms to make additional payments for new technologies were implemented rather expansively. For example, CMS liberalized a criterion for qualifying as a pass-through item under the category of new drugs, devices or biologicals, requiring that the estimated cost of the item exceed 10% (instead of 25%) of the applicable APC payment rate.[10] In addition, CMS indicated that for 2000 and 2001, it would not have sufficient data to estimate pass-through payments and thus would not impose any reduction on pass-through payments.[11] Finally, Congress stepped in to expand the eligibility criteria for devices by allowing devices that were paid as outpatient services prior to 1997 to qualify for pass-through payments.[12] All of these developments resulted in more payment for new technologies and thus promoted their use by hospitals in the outpatient setting.

These expansions, however, came at a price. With more technologies receiving additional payments from Medicare as part of the pass-through scheme, there was increased pressure on CMS to enforce the statutory limit on pass-through reductions. CMS reacted by imposing a pro rata reduction of 63.6% in 2002 on payments for all pass-through products (which results in considerably less than a 63.6% reduction in payment for eligible items).[13] While the reduc-

[9] 66 Fed. Reg. 59,856, 59,902–03 (Nov. 30, 2001).

[10] 65 Fed. Reg. 47,670, 47,673 (Aug. 3, 2000). Lowering the threshold allowed a significant number of additional devices to qualify for additional payments under Outpatient PPS. 66 Fed. Reg. 55,850, 55,853 (Nov. 2, 2001).

[11] 65 Fed. Reg. 18,434, 18,481 (April 7, 2000).

[12] BIPA § 402(b)(1) (amending 42 U.S.C.A. § 1395l(t)(6)(A)(iv)(II)). This legislation also required CMS to use category codes to determining eligibility of devices for pass-through payments, rather than approving devices individually.

[13] 67 Fed. Reg. 9,556 (Mar. 1, 2002). Because of certain technical issues, the reduction is only effective for the last three quarters of calendar year 2002. The reduction does not impact payments for services paid as new technologies under Outpatient PPS.

tion does decrease Medicare payments for pass-through products, the fact remains that, in 2002, Medicare will continue to make additional payments for qualifying drugs, biologicals, and devices, unlike what occurs under Inpatient PPS.

With respect to new devices, however, the prospects for additional payments as pass-through items under Outpatient PPS have diminished. As noted earlier, CMS determines whether devices are eligible for pass-through payments by looking at categories of devices, rather than individual devices. In a final rule published on November 2, 2001, CMS stated that it will only establish a new category code for devices that, in addition to meeting previously existing criteria, present a substantial improvement in medical benefits and satisfy the more stringent insignificant cost test that CMS first implemented.[14]

The substantial improvement criterion for device category codes mirrors the substantial improvement criterion that CMS uses to determine if a new technology merits additional payments under Inpatient PPS (as discussed above) and is likely to be the most limiting factor in the creation of new category codes. Thus, after a positive start with respect to recognizing the costs of new technologies under Outpatient PPS, the future looks to be less inviting for new device technologies used in the outpatient setting. Even so, there should be more opportunities to receive additional payments for new technologies and new drugs and biologicals used in the outpatient setting than in the inpatient setting.

V. NEW TECHNOLOGY FURNISHED IN PHYSICIAN OFFICES

§ 39:7 Generally

As with payment for new technology to hospitals, physician reimbursement for new technology is hampered by the length of time needed to obtain an appropriate code for any new service. CPT codes, approved by the American Medical Association ("AMA") and adopted by CMS, are used to define physician services. CMS also has alpha-numeric HCPCS codes for certain, limited physician services. Generally, the AMA will not consider approving a new physician

[14] 66 Fed. Reg. 55,850, 55,852–53 (Nov. 2, 2001). The insignificant cost test requires that the estimated cost of the devices in the category exceed 25% of the applicable APC amount and that the difference between the estimated cost of devices in the category and the portion of the APC payment rate associated with the device exceeds 10% of the APC payment rate.

service for a CPT code until the new technology has received FDA approval. The AMA also requires at least one article on a new technology in an U.S. peer-reviewed journal. Without market data demonstrating widespread usage, it might be difficult to obtain a new CPT code.

The timing of the AMA meetings to determine new codes further compounds the dilemma for a new technology. Applications for new CPT codes are considered by the AMA's CPT Editorial Panel, consisting of 17 members, at its quarterly meetings every year. The meetings usually are in February, May, August, and November. New or revised CPT codes (so-called Category I codes) are effective January 1 of each year. However, a new code must be adopted at or before the February Editorial Panel meeting to become effective the following January. Therefore, for example, a new code that is approved at the May 2002 Editorial Panel meeting will not go into effect until January 2004 — not the following January 2003.

Because of the delay, the AMA has created a new category of CPT codes called Category III codes. These codes are temporary tracking codes for new and emerging technologies. FDA approval is not required for a Category III code. The adoption of these Category III codes also is considered at the Editorial Panel's quarterly meetings. Once adopted these Category III codes become effective the following January 1 or July 1, whichever is sooner, by appearing on the AMA's CPT website.

Category III codes are intended to facilitate data collection on new services and procedures. However, many payers may not reimburse for Category III codes. Indeed, CMS leaves Medicare coverage and reimbursement of these codes to the discretion of individual carriers. Moreover, a Category III code will not automatically become a Category I code, but rather must be approved for Category I by the Editorial Panel.

Once the AMA CPT Editorial Panel has approved a new Category I code, other AMA Committees must review the new service and recommend relative value units for the new technology that will be used by payers, including Medicare, to determine reimbursement amounts. The AMA's Resource-Based Relative Value Scale Update Committee ("RUC") recommends physician work values to CMS and the AMA's Practice Expense Advisory Committee ("PEAC") recommends practice expense values. Practice expense would include the cost to the physician for the new technology's equipment and supplies.

Since 1992, Medicare has paid for physician services based on a resource-based relative value fee schedule.[1] Reimbursement is based on the sum of the relative values for the three components of a physician service — work, practice expense, and malpractice expense — multiplied by a dollar conversion factor that is set by CMS each year. Many other payers reimburse for physician services based on Medicare's fee schedule or some percentage thereof. When the fee schedule was first implemented in 1992, only the relative value units assigned to the physician work component were truly resource-based. The AMA's RUC recommends physician work values to CMS for existing CPT codes under review and for new codes.

The practice expense component of physician services initially was based on historical charges for services. Thus, a new technology would not be adequately valued under a historical charges system. However, in 1994, Congress enacted a law that required CMS to develop a methodology for a resource-based system for determining the practice expense relative value units for each physician service.[2] Properly implemented a resource-based system might reflect appropriate values for new technology.

When the proposed practice expense resource-based values were published in the *Federal Register* for comment in 1997,[3] there were winners and losers in the physician community. Essentially, hospital-based services, including many surgical procedures, faced steep payment reductions, because the actual practice costs to physicians for hospital-based procedures are fairly insignificant.

Before even the close of the comment period for the proposed rule, Congress in the Balanced Budget Act of 1997 delayed implementation of the resource-based practice expense system for one year until January 1, 1999 and also required the new system to be phased in over a four-year period.[4] Thus, beginning on January 1, 2002, the resource-based practice expense methodology is fully phased in. In developing the resource-based practice expense values, CMS relies on three sources of information. First the AMA has Socioeconomic Monitoring System ("SMS") data that track aggregate specialty

[Section 39:7]

[1] 42 U.S.C.A. § 1395w-4.

[2] Section 121 of the Social Security Act Amendments of 1994, Pub. L. No. 103–432.

[3] 62 Fed. Reg. 33,196 (Jun. 18, 1997)(proposed rule); 62 Fed. Reg. 59,103 (Oct. 31, 1997) (final rule).

[4] Section 4505(a), Balanced Budget Act of 1997, Pub. L. No. 105–33 (amending 42 U.S.C.A. § 1395w-4(c)(2)(iii)).

practice costs. Second, CMS convened panels of physicians, the Clinical Practice Expert Panels ("CPEPs") from various specialties to compile and review proposed practice costs per service. Third, the AMA's PEAC also reviews practice expense costs for existing and for new codes and provides recommendations to CMS regarding these values.

Under the resource-based system, CMS provides separate relative value units for each physician service based on whether the service is performed in a facility or non-facility (physician office) setting. The practice expense component for a service is larger for the non-facility (physician office) setting, because in this setting the physician must bear the practice costs such as equipment, supplies, overhead, drugs, etc. In a facility, those practice costs usually are borne by the facility and not the physician. If CMS is provided with the correct costs for any given new technology, then these costs, in theory, should be reflected in the practice expense component for the new code. However, in actuality, the costs of most new technology are not adequately included in the resource-based practice expense values. Nevertheless, the resource-based methodology does provide an opportunity for new technology to be more fairly reimbursed.