The RAP Sheet

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Table of Contents

AMERICAN HEALTH LAWYERS ASSOCIATION

Leading Health Law to Excellence through Education, Information, and Dialogue

Renewed Interest in Hospital/Physician Gainsharing Programs

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I. Introduction

Recent actions of both the Office of the Inspector General (OIG) and the Medicare Payment Advisory Commission (MedPAC) are likely to renew interest in hospital/physician gainsharing programs. The OIG has issued six favorable advisory opinions involving hospital/physician gainsharing programs this year.[1] In its report to Congress dated March 2005, MedPAC has recommended that Congress grant the Secretary of the Department of Health and Human Services the authority to permit and regulate gainsharing arrangements between hospitals and physicians.[2] It is likely that these recent actions will cause many hospitals that previously did not offer any such programs to reconsider their positions in light of the favorable OIG guidance and MedPAC's recommendations to Congress.

This article will provide a brief overview of gainsharing programs, review prior guidance and a prior advisory opinion issued by the OIG with respect to such programs, and provide a concise summary of the recent advisory opinions issued by the OIG.

II. Defining "Gainsharing"

Gainsharing programs are designed to align the economic incentives of hospitals and physicians to provide cost effective care and maintain or improve quality of care and patient satisfaction. Additionally, gainsharing programs allow physicians to share in the cost savings through some combination of a percentage payment, hourly fee, or fixed fee, and to play a significant role in the planning process to achieve those savings. From a hospital's perspective, gainsharing programs help reduce costs through standardization and economic efficiencies in operations; from a physician's perspective, gainsharing programs provide a financial incentive for physicians to cooperate with hospitals in developing and implementing programs designed to reduce a hospital's operating costs without negatively impacting the quality of care provided to hospital patients. Gainsharing programs attempt to modify physician behavior in order to control costs and increase margins on hospital business. These gainsharing programs typically include features to safeguard quality of care, which makes good business sense and helps control malpractice liability exposure. Many hospitals also believe that such programs are useful in ensuring greater access to care by allowing the hospital to recruit or retain top medical talent that is needed to effectively operate high-end programs, and to generate improved margins that can be used to fund care provided to indigents or low-income populations.

Although each gainsharing plan has its own individual characteristics, there are many similarities that are useful to consider in analyzing the relevant legal risks of these programs. Typical gainsharing programs include a payment to develop best practices in the physicians' specialty, covering such areas as uniformity in supplies and devices, length of stay, and clinical protocols. Physicians are then paid a management or oversight fee to implement and assess the progress of and refine the best practices. Some program designs call for only a fixed fee payment or only an incentive payment in the implementation phase, while others include both a fixed, periodic management fee for the oversight and redesign functions and an incentive payment tied to the success of implementation in achieving 1the program's goals of cost savings, quality of care, and patient satisfaction. Those incentives have been structured as a percentage of the cost savings, fixed dollar amounts for reaching certain target thresholds for one or more of the program goals, and even hourly payments for increased efforts required to implement the best

Continued on page 2

Continued from page 1

practices as compared to the time required to proceed under the old status quo. To avoid continued payments for behavior that has already been modified, well-designed gainsharing programs are typically of limited duration or, if more complex and creative, provide for annual rebasing of the cost, quality, and satisfaction thresholds so that physicians are rewarded for continuous improvement rather than maintaining a new status quo.

III. OIG Guidance

A. OIG Special Advisory Bulletin

On July 8, 1999, the OIG released a Special Advisory Bulletin entitled "*Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries*" (SAB).[3] The SAB provided a long-awaited and unexpectedly (for many observers) negative response from the OIG with respect to gainsharing arrangements. The OIG concludes that gainsharing arrangements that involve payments by or on behalf of a hospital to physicians with clinical care responsibilities, directly or indirectly, to induce a reduction or limitation of services to Medicare or Medicaid patients are a violation of the civil money penalty provisions of the Social Security Act (CMP Law).[4]

Prior to the publication of the SAB, the OIG had received several requests for formal advisory opinions on whether gainsharing arrangements were in violation of the Medicare anti-kickback statute. Instead of ruling on any of these individual requests, the OIG issued the SAB stating that no advisory opinions would be forthcoming because the OIG had reached the conclusion that gainsharing programs violated the CMP Law.[5]

According to the OIG, for a violation of the CMP Law to occur, payment need not be tied to an actual diminution in care, so long as the hospital knows that the payment may influence the physician to reduce or limit services to his/her patients. Nor is the proscription limited to a reduction or limitation in medically necessary care.[6]

The OIG notes that "gainsharing arrangements that directly or indirectly provide physicians financial incentives to reduce or limit items or services to patients that are under the physicians' clinical care are precisely the kind of physician incentive plans that Congress prohibited when it enacted section 1128A(b)(1) of the Act." Further, in the opinion of the OIG, there is "no meaningful difference between the kinds of incentive plans proposed in 1986 at the time of enactment of section 1128A(b) and the variants being promoted by hospitals and healthcare consultants today."[7] Although the OIG recognizes that hospitals have a legitimate interest in enlisting physicians in their efforts to eliminate unnecessary costs and notes that savings that do not affect the quality of patient care may be generated in many ways including: (1) substituting lower costs but equally effective medical supplies, items, or devices, (2) re-engineering hospital surgical and medical procedures, (3) reducing utilization of medically unnecessary ancillary services, and (4) reducing unnecessary lengths of stay, the SAB states that "the plain language of section 1128Ab)(1) of the Act prohibits tying the physicians' compensation for such services to reductions or limitations in items or services provided to patients under the physicians' clinical care."[8]

According to the OIG, it is still possible to structure arrangements that align the interests of physicians and hospitals to achieve cost savings without violating the CMP Law. An example of such an arrangement would be a personal services contract where a hospital pays a physician based on a fixed fee that is fair market value for services rendered rather than a percentage of cost savings (and the payment cannot be contingent on achieving cost savings).[9] The OIG notes, however, that any such arrangements must still satisfy the requirements of the Medicare anti-kickback statute.[10]

The issuance of the SAB had a chilling effect on the development and implementation gainsharing programs. To the surprise of many, in January of 2001 the OIG issued a favorable advisory opinion involving a gainsharing program.

B. OIG Advisory Opinion No. 01-01

In OIG Advisory Opinion No. 01-1, the OIG reviewed a proposed arrangement in which a hospital would share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures. The program and the OIG's analysis are similar in many respects to the six favorable gainsharing opinions issued this year.

Under the program, the hospital would pay the surgeon group a share of the first year cost savings directly attributable to specific changes in the surgeon group's operating practices. In general, under the program, the surgeon group would change its current operating room practices to curb the inappropriate use or waste of medical supplies. The changes to the group's operating room practices involved opening packaged items only as needed during a procedure, the substitution, in whole or in part, of less costly items for items currently being used by the surgeons, and limitation of the use of aprotinin—a medication given to many surgical patients preoperatively to prevent hemorrhaging—to patients that are at higher risk of perioperative hemorrhages indicated by objective clinical standards.

As is the case in the six recently issued opinions, the proposed program contained several safeguards intended to protect against inappropriate reductions in services. For example, with respect to the substitution recommendations, the program would utilize objective historical and clinical measures reasonably related to the practices and patient population at the hospital to establish a "floor" below which no savings would accrue to the surgeon group.

Under the proposed program, the surgeon group would receive 50% of the cost savings achieved by implementing the recommendations for a period of one year. In addition, payments to the surgeon group will be limited to the same

types of limitations inherent in the arrangements considered in the six recently issued advisory opinions.

In reviewing the proposed program, the OIG concluded that, except for the unopened surgical tray items, the recommendations set forth in the program implicate the CMP in that the program constitutes an inducement to reduce or limit the current medical practice at the hospital. Nevertheless, the OIG noted that the program includes several safeguards such that the OIG would not seek sanctions against the parties under the CMP Law. These safeguards are virtually identical to those described in the recently issued advisory opinions.

The OIG then reviewed the proposed program in light of the anti-kickback statute. The OIG noted that like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, it is concerned that the proposed program could be used to disguise remuneration from the hospital to reward or induce referrals by the surgeon group. Specifically, the proposed program could encourage the surgeons to admit federal healthcare program patients to the hospital, since the surgeons would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the hospital's payment, dependent on cost savings.

The OIG then went on to state that although it believes the proposed program could result in illegal remuneration if the requisite intent to induce referrals were present, it would not impose sanctions in the particular circumstances presented by the proposed arrangement for the following reasons: (i) the circumstances and safeguards of the proposed program reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians; (ii) the program eliminates a risk that it will be used to reward cardiologists or other physicians who refer patients to the surgeon group because the surgeon group is the sole participant in the program and is composed entirely of cardiac surgeons; and (iii) the program specifically sets forth the particular actions that will generate the costs savings on which the payments are based, which actions represent a change in operating room practice for which the surgeon is responsible and will have liability exposure—moreover, the payments will represent a portion of one year's worth of cost savings and will be limited in amount (*i.e.*, the aggregate cap), duration (*i.e.*, the limited contract term), and scope (*i.e.*, the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). These reasons also are noted in the anti-kickback analysis of the arrangements considered in the recently issued advisory opinions discussed elsewhere in this article. The OIG went on to conclude that the proposed program would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals was present, but that, based on the totality of the facts present in the proposed program as described in the request, the OIG would not request or seek sanctions for violation of the anti-kickback statute.

IV. Recent OIG Advisory Opinions

In a series of six nearly identical advisory opinions issued this year, the OIG has sparked renewed interest in gainsharing arrangements between hospitals and physicians.[11] As was the case in OIG Advisory Opinion No. 01-01, the OIG concludes that each of the arrangements considered would constitute an improper payment to induce a reduction or limitation of services in violation of the CMP Law, and would potentially generate prohibited remuneration under § 1128B(b) of the federal anti-kickback statute if the requisite intent was present. Nonetheless, the OIG concludes, as is does in Advisory Opinion No. 01-01, that it will not impose administrative sanctions on the requestors of any of the opinions in connection with the contemplated gainsharing arrangements.

A. Overview of Arrangements

Three of the advisory opinions consider gainsharing arrangements between hospitals and groups of cardiac surgeons. The other three advisory opinions focus on gainsharing arrangements between hospitals and groups of cardiologists. Under the proposed arrangements, the hospital would share with the cardiologists or the cardiac surgeons, approximately 50% of the first year cost savings derived by the hospitals as a result of the implementation by the physicians of specific cost-savings measures in cardiac surgery and cardiac catheterization laboratory procedures, respectively. All of the cost saving measures were developed by an independent administrator after studying historic practices and potential cost savings at the hospitals related to the use of certain supplies.

B. The Cost Savings

With respect to the cardiac surgeons, the cost savings measures focus on recommendations such as: (i) opening certain packaged items (such as surgical trays, supplies, and cell saver disposable units) only as needed during surgery, (ii) performing blood cross-matching only as needed when patients require transfusions, (iii) substituting less costly items for items then being used by the surgeons, and (iv) standardizing various cardiac devices as medically appropriate. With respect to the cardiologists, cost savings measures focus on product standardization, limiting the use of certain vascular closure devices to an "as needed" basis for inpatient coronary interventional and diagnostic procedures, and substituting less costly items in connection with the use of contrast agents.

The OIG favorably notes that the proposed arrangements with the cardiac surgeons and with the cardiologists each provide for safeguards to protect against improper reductions in service. For example:

1. Objective historical and clinical measures will be used to create a floor above which no savings can be earned by the physicians. For example, if the cellsaver package is set up for 100% of the cases but is used only in 30% of the cardiac procedures included in the arrangement, the car-

Continued on page 4

Continued from page 3

diac surgeons (in this example) will receive no portion of any savings derived from reduced use of cell-savers beyond the 30% floor.

2. Notwithstanding product standardization initiatives, individual physicians will select the most appropriate cardiac device for patients on a case-by-case basis and the full range of such devices would remain available.
3. Payments to the physicians will be limited such that: (i) no cost savings will be shared to the extent that the volume of procedures payable by a federal healthcare program during the term of the arrangement exceeds the historical volume of comparable procedures payable by a federal healthcare program; (ii) physicians who steer more costly patients to other hospitals to maximize their return under the proposed arrangements (as determined by deviations in the case severity, age, and payors of patients treated under the proposed arrangement) will be terminated from participating in the proposed arrangement; and (iii) the aggregate payment to the physicians will not exceed 50% of the anticipated savings set forth in projections made for the proposed arrangement.
4. Patients will receive written notice of the proposed arrangement including the fact that the physicians' compensation is based on a percentage of the hospital's savings.

C. OIG's Legal Analysis

The OIG acknowledges that, under the current reimbursement system, hospitals (not physicians) bear the burden of excess costs inherent in the services subject to the proposed arrangement, and that gainsharing arrangements seek to align incentives by offering physicians a share of cost savings in exchange for implementing cost savings strategies. The OIG also recognizes that properly structured gainsharing programs can have legitimate business and medical purposes and can increase efficiency, decrease waste, and improve hospital profits. On the down side, however, the OIG notes that gainsharing programs can influence physicians to withhold patient care, refer more costly patients to other hospitals that do not have gainsharing programs, trigger payments in exchange for referrals, and foster unfair competition among hospitals eager to foster physician loyalty and attract more referrals.

D. CMP Law

Despite the adverse CMP implications of the proposed arrangements, the following features persuade the OIG not to pursue CMP sanctions against the requestors:

1. The specific cost-saving actions and consequential savings are clearly and separately identified. The design of the program allows for public scrutiny and physician accountability for adverse effects based on differences in patient treatment.
2. Credible medical support indicates that implementation of the recommendations will not adversely affect patient care and plans exist for periodic review of the program to ensure that this remains true.
3. Payments under the proposed arrangement are based without regard to the patients' insurance, and are subject to a cap on payment based on payments for federal healthcare program procedures. Additionally, cost savings are calculated on actual out of pocket hospital acquisition costs.
4. The arrangements protect against inappropriate reductions in service by relying on objective historical and clinical measures to create baseline thresholds above which no savings will be allocated to the physicians.
5. Notwithstanding product standardization aspects of the proposed arrangements, physicians still have available the same array of devices as were available prior to the program.
6. Written disclosures to patients of the physician's involvement in the arrangement are required.
7. Financial incentives are limited in duration and amount and are distributed on a per capita basis, which reduces incentives to generate disproportionate cost savings on an individual basis.

The OIG notes that its decision not to impose sanctions is an exercise of its discretion consistent with its previously issued SAB and the CMP Law. The OIG also notes that the proposed arrangements are "markedly different" from many gainsharing programs, particularly those that pay physicians a percentage of generalized cost savings not tied to lower, identifiable cost-lowering actions. The programs that the OIG indicates have heightened risk are those for which:

1. There is no demonstrable direct link between individual action and any decrease in hospitals' out of pocket costs.
2. Individual actions giving rise to the savings are not specifically identified.
3. Insufficient safeguards exist against the risk that other unidentified actions (*e.g.*, premature hospital discharge) actually account for the savings.
4. Quality of care indicators are of questionable validity and statistical significance.
5. No independent verification exists of cost savings, quality of care indicators, or other essential aspects of the arrangement.

E. The Anti-Kickback Statute

In analyzing the arrangements under the federal anti-kickback statute,[12] the OIG notes that the personal services safe harbor cannot be met because the physicians would be paid on a percentage basis; therefore, their compensation would not be set in advance as required to satisfy that safe harbor. Noting that the failure to fit within a safe harbor is not fatal, the OIG concludes that even though the proposed arrangement could result in illegal remuneration if the requisite intent is present, it will not impose sanctions under the federal anti-kickback statute with

respect to the proposed arrangements, taking comfort in the following safeguards:

1. The structure of the proposed arrangement reduces the likelihood that it will be used to attract referring physicians or increase referrals from existing physicians because participation is limited to physicians already on the medical staff.
2. Potential savings derived from procedures for federal healthcare program beneficiaries will be capped based on the prior year's admissions of such beneficiaries.
3. The contract term is limited to one year, reducing any incentive for physicians to switch facilities.
4. All patient admissions will be monitored for changes in patient age, severity, and payor mix.
5. The proposed arrangement specifies which actions will generate the cost savings on which the payments are based.
6. Limiting the physician participants in the group to cardiac surgeons or cardiologist, respectively, eliminates the risk that the arrangement will be used to reward other physicians who refer to the cardiac surgeons or cardiologists.
7. Each of the changes to be implemented carries increased risk of liability for the physicians.
8. The payments to be made to the physicians represent a portion of one year's worth of cost savings, are limited in amount because they are subject to a cap, are limited to a one-year duration and are limited in scope in terms of the amount of savings that can be achieved. The OIG also notes that programs of longer duration, are likely to require additional or different safeguards.

F. The Stark Law

Significantly, the OIG notes that the gainsharing arrangements at issue implicate the physician self-referral laws at § 1877 of the Social Security Act (Stark Law). The OIG declined to express any opinion regarding those implications under the Stark Law, however, because that law is outside of the scope of the OIG's advisory opinion authority.

To the extent that physicians considering participation in gainsharing programs also make referrals for designated health services to the hospital participants in such programs, the parties need to ensure that the financial relationships involved fit within an exception to the Stark Law. For example, the personal services exception to the Stark Law, among other requirements, requires the compensation to be paid to the physicians over the term of each arrangement to be set in advance. The Stark Law regulations specifically recognize that compensation can be considered "set in advance" if "a specific formula for calculating the compensation is set in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid." 42 C.F.R. § 411.354(d)(1). The formula must be specified in sufficient detail to allow for objective verification and cannot be changed during the coverage of the agreement to reflect the volume or value of referrals or other business generated between the parties. Thus, it may well be possible to structure a gainsharing program that meets the Stark Law personal services exception or, potentially, other Stark Law exceptions such as the fair market value exception or the indirect compensation exception.

V. Conclusion

Although the recent advisory opinions discussed above can be relied upon only by their requestors, the opinions reflect a recognition by the OIG of the acceptability and potential benefits of properly structured gainsharing programs. Hospitals and physicians considering gainsharing programs should take note of these opinions and the various safeguards included therein to ensure that patient care is not adversely affected by the implementation of a gainsharing program. They also should note the distinction drawn by the OIG between gainsharing programs that provide for specific, identifiable, and verifiable cost savings coupled with an array of safeguards to protect patient care and other general gainsharing programs tied to overall cost savings. Moreover, in the absence of congressional action that specifically permits hospitals and physicians to enter into gainsharing arrangements, hospitals and physicians may wish to obtain an advisory opinion from the OIG prior to instituting any such arrangements.

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Endnotes

1 The full text of Advisory Opinions Nos. 05-01, 05-02, 05-03, 05-04, 05-05, and 05-06 are available on the OIG's website at www.hhs.gov/oig.

2 The full text of the MedPAC report is available on MedPAC's website at www.medpac.gov.

3 The full text of the Special Advisory Bulletin is available on the OIG's website at www.hhs.gov/oig/frdalrt/gainsh.htm.

4 The CMP Law (§ 1128A(b)(1) of the Social Security Act) prohibits a hospital from making a payment, directly or indirectly, to induce a physician to reduce or limit services to federal healthcare beneficiaries under the physician's direct care. A hospital that makes, and any physician who accepts, such payments is subject to civil money penalties of up to $2,000 for each patient covered by the improper payments.

5 It is important to note that the plans reviewed by the OIG pursuant to the requests for advisory opinions purportedly included all of the safeguards recommended in the GAO report and noted in the 1994 proposed Hospital Regulations. *See* Kevin McAnaney, remarks at teleconference: "On The Ropes: OIG Rejects Gainsharing," presented by the American Bar Association Center for Continuing Legal Education and the Health Law Section of the American Bar Association, August 3, 1999 (hereinafter, Remarks of McAnaney). At the time, McAnaney was the Chief of the Industry Guidance Branch, Office of Counsel to the Inspector General and was the principal author of the SAB.

6 The hospital physician incentive plan prohibition is triggered when any services are reduced or limited, whether or not they are medically necessary services; however, the

Continued on page 6

Continued from page 5

managed care physician incentive plan prohibition is triggered only when medically necessary services are reduced or limited. Section 1128A(a)(1)(E) of the Social Security Act (enacted as 42 U.S.C. § 1320a-7a(a)(1)(e)), however, provides for a $10,000 civil money penalty for knowingly presenting or causing the presentation of a claim to Medicare or Medicaid for a "pattern of medical or other items or services that a person knows or should know are not medically necessary." Moreover, OIG has suggested that this difference in the statutes alone is not determinative. *See* Remarks of McAnaney, *supra*.

[7] SAB at p. 3.

[8] *Id.*

[9] *See* Remarks of McAnaney. The OIG would distinguish between paying physicians to develop clinical guidelines and actually paying the physicians to follow the guidelines. For example, the OIG would likely look with favor on the payment of a justifiable hourly rate for services actually provided in designing (and perhaps testing) clinical pathways, protocols, and best practices; however, an arrangement whereby a physician group was to receive a value sensitive payment, such as $500,000 for their efforts in achieving a cost savings of $2,000,000, would likely be viewed as a prohibited payment to induce a reduction in clinical care.

[10] SAB at p. 3.

[11] OIG Advisory Opinions Nos. 05-01, 05-02, 05-03, 05-04, 05-05, and 05-06.

[12] The federal anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal healthcare program.

Practice Group Luncheons

at the 2005 Annual Meeting

SUNDAY, JUNE 26

In-House Counsel
You'll be entertained by real-life, too-weird-to-be-true stories told by fellow health law attorneys competing for the Sixth Annual Golden Ferret Award. Listen to your colleagues as they recount their strangest work-related escapades.

MONDAY, JUNE 27

Fraud and Abuse, Self-Referrals, and False Claims and Regulation, Accreditation, and Payment
Combined Luncheon
More information will be available soon.

Tax and Finance
Topic: Roundtable Discussion on Practical and Substantive Tax Law Matters
Moderators: Douglas Anning, *Polsinelli Shalton Welte Suelthaus PC, Kansas City, MO*;
Linda Moroney, *Michael Best & Friedrich, Milwaukee, WI*;
Jim King, *Jones Day, Columbus, OH*
John Beard, *Baker Donelson, Jackson, MS*
Gerry Griffith, *Honigman Miller Schwartz & Cohn, Detroit, MI*

Teaching Hospitals and Academic Medical Centers
Topic: Risk Management and Teaching Hospitals
Presenter: Mark Kadzielski, *Fulbright & Jaworski LLP, Los Angeles, CA*

TUESDAY, JUNE 28

Hospitals and Health Systems and Health Information and Technology
Combined Luncheon
Topic: Will the Law Catch Up to or Delay E-prescribing?
Presenters: Jodi Goldstein Daniel, *Office of General Counsel, Civil Rights Division, DHHS, Washington, DC*
Cynthia F. Wisner, *Assistant General Counsel, Trinity Health, Novi, MI*
David W. Grauer, *Squire Sanders & Dempsey, Columbus, OH*

HMOs and Health Plans
Topic: Managing CMS Program Contracts: Maximizing Opportunities, Reducing Risks and Dealing with the Government
Presenters: Kenneth M. Bruntel, *Crowell & Moring LLP, Washington, DC*
Ellen Hunt, *Vice President, Compliance, Health Care Services Corporation, Inc., Chicago, IL*

Long Term Care
Topic: Medicare Part D Action Plan for LTC Facilities
Presenter: Nancy Taylor, *Greenberg Traurig LLP, Washington, DC*

Physician Organizations
Topic: An open floor discussion addressing:
- Challenges of on-call coverage, including requirements for taking call and trends in payment for on-call coverage
- Economic credentialing
- Electronic healthcare records-implementation challenges and payment mechanisms

Moderators: Charlene McGinty, *Powell Goldstein LLP, Atlanta, GA*
Lisa Taylor, *St. John & Wayne LLC, Newark, NJ*
Cindy Reisz, *Bass, Berry & Sims PLC, Nashville, TN*
David J. Hyman, *Sneed Lang PC, Tulsa, OK*

WEDNESDAY, JUNE 29

Labor and Employment
Topic: Sexual Harassment Claims Between Doctors and Nurses
Presenter: Lynn R. Goodfellow, *Foley & Lardner LLP, San Diego, CA*

Medical Staff, Credentialing, and Peer Review
Topic: Hearing Officer Dilemma: How to Select a Hearing Officer following *Yaqub v. Salinas Valley Memorial Healthcare System*
Presenter: Michael A. Cassidy, *Tucker Arensberg PC, Pittsburgh, PA*

Antitrust
Topic: Update on Healthcare Antitrust Developments
Moderator: Arthur Lerner, *Crowell & Moring, Washington, DC*

Healthcare Liability and Litigation
Topic: Tort Reform Update: The Latest Developments
Presenters: Jack Schroder, *Alston & Bird LLP, Atlanta, GA*
Curtis Rooney, *American Hospital Association, Washington, DC*

To Register for any of the Practice Group luncheons go to www.healthlawyers.org/securedforms/prog_05annual_form.cfm

CMS Issues New Claims Appeals Regulations

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The Centers for Medicare and Medicaid Services (CMS), on March 8, 2005, issued an interim final rule that establishes new regulations implementing a sweeping set of changes to the existing Medicare claims appeals process.[1] Mandated by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the changes aim to substantially improve and streamline the Medicare appeals process. The new regulations can now be found in one location in subpart I of part 405 of C.F.R., separate from the existing appeals regulations.

The significant, noteworthy changes that will impact the provider community are summarized below.

I. Uniform Process for Part A and Part B Claims Appeals

Under the final rule, appeals for both Part A and Part B claims are now consolidated into one uniform process. In addition, the final rule imposes on the adjudicators decision making timeframes for the appeals at each level, and significantly, provides for an option to escalate the appeal process to the next level if a decision is not made within the required timeframe by the current adjudicator. Further, the final rule requires appeal notices issued by the adjudicator at each level to contain defined substantive elements. Significantly, the final rule expands the limitation of initial determinations that can be appealed by providers—under the final rule, providers may appeal initial determinations to the same extent as beneficiaries.

The uniform appeals process mandated by BIPA and MMA are as follows. Upon receipt of an initial determination from a contractor, a provider's appeal of Part A or Part B claims now proceed according to the following five steps:

1. Redetermination
2. Reconsideration
3. Administrative Law Judge (ALJ) Hearing
4. Medicare Appeals Council (MAC)
5. Federal District Court

A. Redetermination

The redetermination level of the appeals process entitles the provider dissatisfied with the initial determination to an independent desk review by the contractor, regardless of the amount in controversy. The redetermination level of appeal consists of a fresh examination of all the issues involved in the initial determination by the contractor. The dissatisfied provider's request for a redetermination must be made in writing and filed with the contractor indicated on the notice of initial determination within 120 days from the date of the receipt of the notice of initial determination.

The contractor must make a decision within 60 calendar days from the date the contractor receives the request from the provider. At the redetermination stage, the provider does not have an option to escalate the case to the next level of appeal should the contractor fail to issue a decision within 60 days. With the exception of the filing and decision making time frames however, the final rule did not make major changes to the existing redetermination process.

B. Reconsideration by Qualified Independent Contractors (QICs)

Perhaps the most significant aspect of the final rule is the implementation of the reconsideration level of appeal by QICs. QICs are entities that possess sufficient training and expertise in medical science and legal matters to make reconsiderations and are independent of the contractors.

A provider dissatisfied with the redetermination by the contractor has a right to appeal the decision to a QIC for reconsideration, regardless of the amount in controversy. A reconsideration by the QIC is an independent, on the record review of an initial determination, including the redetermination and all issues related to payment of the claim.

A reconsideration request must be filed with a QIC within 180 calendar days from the date of the receipt of the notice of redetermination from the contractor. The request must be filed with the QIC indicated on the notice of redetermination and must be in writing.

The QIC must make a decision within 60 calendar days from the date it receives a timely filed reconsideration request. If the QIC is not able to complete the reconsideration within 60 days, it must notify the provider that it is not able to complete the reconsideration by the deadline and allow the provider to escalate the appeal to an ALJ. If the provider does not escalate the appeal to an ALJ, the QIC continues to process the reconsideration to its conclusion.

C. ALJ Hearing

A provider dissatisfied with the QIC's reconsideration may appeal to an ALJ for a hearing. The request for a hearing must be made in writing and filed with the entity specified in the QIC's reconsideration decision within 60 days after the date of receipt of notice of the reconsidered determination. The final rule specifies the elements that must be contained in a valid request for reconsideration. The amount in controversy requirement for requests for an ALJ hearing will be based on the percentage increase in the medical care component of the consumer price index for urban consumers.

The ALJ considers all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a provider's favor. The ALJ also may consider a new issue at the hearing provided a notice is given to the provider about the consideration of the new issue any time before the start of the hearing. In addition, if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, the ALJ may consider the issue after giving notice to the provider before the hearing.

The ALJ must issue a decision within 90 days of the receipt of the hearing request. If the ALJ fails to issue a decision within

this timeframe, the provider may escalate the appeal to the MAC. The final rule also contains a detailed set of rules governing the ALJ hearing process.

D. MAC

A provider or any other party to the ALJ hearing may request that the MAC review an ALJ's decision. An appeal to the MAC must be in writing and submitted within 60 days of the receipt of the ALJ hearing decision. The MAC reviews the case *de novo*.

The MAC must issue a decision within 90 days of receipt of the provider's request for review. If the MAC fails to do so, the provider has an option to escalate the case to the next level, which would be an action in a federal district court.

E. Federal District Court

A party to a MAC decision or an appellant who requests escalation to a federal district court if the MAC does not complete its review of the ALJ's decision within the applicable timeframe, may obtain a court review if the amount in controversy is $1,000 or more. The provider may file an action in a federal district court within 60 days after the date it receives notice of the MAC's decision.

II. Limitation on the Presentation of Evidence

The final rule contains a significant limitation on the presentation of evidence by providers. When filing a request for reconsideration with a QIC, a provider has an opportunity to present evidence and allegations of fact or law related to the issue in dispute. The evidence may include any missing documentation the contractor identifies in the notice of redetermination. Under the final rule, absent good cause that prevented timely introduction of the evidence, all evidence, including documentation requested in the notice of redetermination, must be presented prior to the QIC's issuance of the notice of reconsideration—failure to do so precludes introduction of that evidence in subsequent levels of appeals. Significantly, this limitation does not apply to CMS. That is, CMS, which may join as a party at the ALJ hearing, may submit evidence at such level of appeal.

The provider is allowed to submit additional evidence during the 60-day decision making timeframe of the QIC—the effect of the additional submission is that the QIC's decision making deadline is extended up to 14 calendar days for each submission. There is no limit on the number of such submissions. The 14-day extension however does not apply to requests for production of documentation made by the QIC.

III. Clinical Experts in the Reconsideration Level

For the first time, the final rule requires a routine reconsideration of medical necessity issues by healthcare professionals. Specifically, if the initial determination involves a finding on whether an item or service is medically reasonable or necessary for the diagnosis or treatment of illness or injury, a QIC's reconsideration process must involve consideration by a panel of physicians or other appropriate healthcare professionals. Further, the reconsideration must be based on clinical experience, the patient's medical records, and medical, technical, and scientific evidence on record.

IV. CMS Intervention at the ALJ Hearing

CMS can now elect to become a party to the ALJ hearing. If it decides to enter a case as a party, CMS is required to provide a notice to that effect to all the parties to the hearing within 10 days of receiving the notice of hearing. As a party, CMS is allowed to file position papers, provide testimony to clarify factual or policy issues, and call witnesses or cross examine witnesses of other parties. Under the final rule, the ALJ is prohibited from requiring CMS to become a party to a case, and cannot draw any adverse inferences if CMS decides not to participate in a case as a party. A limited discovery is permitted only when CMS participates in the hearing as a party.

V. Effective Date of the Final Rule

For all fiscal intermediary redeterminations issued on or after May 1, 2005, providers will have a right to reconsideration by a QIC within 60 days of their request for reconsideration as well as escalation to an ALJ if the reconsideration is not completed timely. For all carrier redeterminations, the effective date will be January 1, 2006. In 2006, all new appeals of Part A and Part B claims will be carried out under the final rule.

Endnotes

1 *See* 70 Fed. Reg. 11420 (March 8, 2005).

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Are Medicare Hospital Payment Policy Changes on the Horizon?

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I. Introduction

With a new Presidential term and Congress now well underway, healthcare policy makers are hard at work in their efforts to improve this country's public health system. While Social Security has received significant early attention and media coverage, policy makers will also be considering several possible Medicare and Medicaid payment changes that would financially impact hospitals.

Enacted in 1983, Medicare's inpatient prospective payment system (IPPS) is now over twenty years old. As a result, some are advocating both technical changes and broader reform to the current diagnosis-related group (DRG) system in order to facilitate its continued effectiveness over the next twenty years. While IPPS reform initiatives are likely to be a topic of debate this year, the first priority will focus on healthcare financing levels proposed during the annual federal budget process, which is now underway.

This article primarily focuses on the President's healthcare budget proposal for fiscal year (FY) 2006 and IPPS reform initiatives that were recently recommended by the Medicare Payment Advisory Commission (MedPAC). Also included is a general discussion of the Senate and House of Representatives Budget Resolutions, which will now be subject to a conference to determine whether a joint budget resolution can be reached.

II. The President's Medicare Budget

On February 7, 2005, the President issued his FY 2006 Budget for the Department of Health and Human Services (DHHS).[1] For Medicare legislative purposes, this Budget does not propose any reductions to the market basket update for IPPS or for Medicare's hospital outpatient prospective payment system (OPPS). This proposal has been favorably received by hospitals, who were concerned that the Administration may have sought a reduction in the IPPS and OPPS update factors for FY 2006 as a means to help pay down the current federal budget deficit.

The Administration's position on the market basket was also a pleasant surprise given that MedPAC had indicated that it would recommend to Congress that Medicare FY 2006 hospital payments for inpatient and outpatient services be updated by the market basket rate minus .4% (which was formally reported in early March 2005).[2] By not proposing any market basket cuts, it appears the Administration would allow the new Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to be fully implemented before other possible Medicare funding cuts would be considered.

However, a closer analysis of the President's Medicare Budget reveals that only to be partially true at best. While the President's Budget does not propose market basket cuts for hospitals, it does target considerable savings (to the tune of $4.6 billion over 5 years) through a significant expansion of Medicare's post-acute transfer payment policy. In fact, CMS' Medicare Fact Sheet states that the President's Budget assumes implementation in 2006 of administrative policies that include the "expansion of post-acute transfer policies to all DRGs to discourage double payment."[3]

Because the Medicare statute permits DHHS to further define the group of DRGs subject to the transfer policy, no legislative action is necessary to effectuate this expansion.[4] This means hospitals should expect DHHS' next IPPS update proposed rule, typically issued in April, to provide detail on the proposed expansion of this payment policy. If such an administrative change were finalized, the expanded transfer policy would go into effect on October 1, 2005. As a result, hospitals will now be gearing up to convince the federal government that further expansion of this policy, which would have a detrimental financial impact on hospitals, is not warranted or appropriate.

III. The President's Medicaid Budget

The President's Medicaid Budget proposal also seeks to achieve significant short term budget savings. The President seeks to rein in so-called "inappropriate" Medicaid spending by $60 billion over five years, including approximately $27 billion in savings to be achieved by restructuring the pharmacy benefit to use Average Sales Price as a key payment component and restricting the use of intergovernmental transfers.[5] The Budget does not address the specific impact of these changes on hospitals. However, the significance of the proposed funding cuts is likely to mean that hospitals will not be spared from a negative financial impact should Congress follow the Administration's Medicaid Budget proposal. While the President also calls for Medicaid coverage expansions of $125.7 billion over ten years, the immediate attention will focus more closely on the substantial cost savings proposals.[6]

IV. Early Budget Action in Congress

On March 10, 2005, the House of Representatives Budget Committee approved a resolution calling for savings targets through reconciliation of $20 billion over five years from the Energy and Commerce Committee (which has jurisdiction over Medicaid and part of Medicare) and $18.7 billion over five yeas from the Ways and Means Committee (which oversees most of Medicare as well as other non-healthcare spending issues). The full House passed this resolution on March 17.

On March 11, the Senate Budget Committee approved its FY 2006 budget resolution, which contains reconciliation language calling for the Senate Finance Committee to cut $15 billion from the federal programs it oversees. Early reports were that $14 billion of that savings may be achieved through Medicaid cuts. Before the full Senate on March 17, an amendment (known as the Smith/Bingaman amendment) was passed that overturned instructions to the Senate Finance Committee to make proposed budget cuts to federal Medicaid spending as contained in the Senate Budget Committee's resolution for FY 2006.

The final budget resolutions passed by the House and Senate will now be subject to a conference between the two chambers to reconcile the bills, with the goal of achieving a joint budget resolution. One key issue to resolve in conference will be the wide gap between the Senate and House views on proper Medicaid funding levels.

V. MedPAC Recommends Wide Ranging IPPS Reforms

In a March 2005 Report to Congress, MedPAC recommends several changes to IPPS "to better reflect the cost of delivering care."[7] A movement to refine the existing DRG system is not new. However, the physician-owned specialty hospital debate has allowed proponents of DRG refinement to champion that approach as *the* solution for the unique issues raised by specialty hospitals. While fundamental changes to IPPS may have some marginal market impact on specialty hospitals, others argue that such a payment solution does not address the conflict of interest concerns that are at the core of the physician-owned specialty hospital model.

Regardless of the current impetus for seeking DRG refinements, MedPAC has now focused the debate on what "changes are needed to improve accuracy of the payment system and thus reduce opportunities for hospitals to benefit from selection."[8] The Commission identified three main problems that need to be addressed. First, the existing "DRG definitions fail to adequately isolate differences in severity of illness associated with substantial differences in cost of hospital inpatient care."[9] This means that the current number of DRGs allows for a wide range of patient severity within one payment group. The thinking behind MedPAC's recommendation is that increasing the number of payment groups based upon more defined severity measures would narrow the cost-to-payment differences currently experienced within existing DRGs.

Second, the DRG relative weights "appear to over- or understate the expected relative costliness of treatment for typical cases in DRGs due to differences in charge setting practices across and within hospitals and differences in the level of costs across hospitals."[10] MedPAC contends that moving from charge-based weights to cost-based weights will help mitigate any skewed outcomes in current weight assignments due to disparate hospital charges.

Third, the extraordinary charges associated with outlier cases appear to inflate the relative weights for DRGs with a disproportionate share of outliers.[11] As MedPAC notes, "the variation in prevalence of high-cost outlier cases contributes to current disparities in relative profitability across and within DRGs," which could create incentives for hospitals to only select low-severity patients for care in these DRGs.[12]

In deciding upon its recommendations, MedPAC analyzed four different options to address these concerns. MedPAC concluded that the best plan to refine IPPS was to adopt all four options in tandem. Three of MedPAC's payment recommendations can be accomplished by DHHS administratively, while the other payment recommendation would require Congressional action. Specifi-cally, MedPAC recommended that DHHS should improve payment accuracy in IPPS by:

1. Refining the current DRGs to more fully capture differences in severity of illness among patients;
2. Basing the DRG relative weights on the estimated cost of providing care rather than on charges; and,
3. Basing the relative weights on the national average of hospitals' relative values in each DRG.[13]

As MedPAC indicates, DHHS has the authority under current law to make these recommended changes to IPPS. In fact, CMS is currently studying a new case mix system, often referred to as APR-DRGs (which stands for All Patient Refinement, a proprietary product licensed by the 3M company), that is designed to further differentiate payment based upon severity of illness. Under the existing APR-DRG model licensed by 3M and studied by MedPAC, the current set of approximately 535 DRGs would be expanded to a number of groups approximately three times that size.

MedPAC also recommended that Congress amend the Medicare statute to give DHHS the authority to adjust the DRG relative weights to account for differences in the prevalence of high-cost outlier cases.[14] Under existing statutory authority for IPPS outliers, DHHS would not be able to implement this recommendation administratively.

Finally, MedPAC indicates that its "analyses show that recommended refinements to Medicare's case mix measurement and outlier financing policies would substantially change IPPS payments for many hospitals."[15] Due to this sudden impact, MedPAC recommends that Congress and DHHS implement the case-mix measurement and outlier policies by using a transition period.[16] The MedPAC report goes on to discuss specific implementation issues that support a phase-in approach.[17]

Because the recommended payment refinements to address the specialty hospital problems would take time for CMS to develop and implement, MedPAC also recommended that the current legislative moratorium on new specialty hospitals be extended until January 1, 2007.[18]

VI. Summary

In summary, while this year's healthcare policy agenda may seem full with issues other than Medicare and Medicaid (for example: Social Security, medical liability reform, and medical error reporting), hospitals still need to pay close attention to legislative and administrative policy proposals that would affect their payments under these programs.

Also, while the IPPS changes proposed by MedPAC are worthy of consideration, DHHS should proceed carefully through this process to ensure that each element of IPPS is reasonable, necessary, and effective in addressing the problems of specialty hospitals for which it is recommended, and will not cause more harm and disruption than the intended benefit. When all of this activity is considered in com-

Continued on page 12

Continued from page 11

bination with the evolving support for an expanded Medicare pay-for-performance initiative, it is critical for hospitals to stay focused on their Medicare and Medicaid issues this year and not be deterred by the amount of attention that other unrelated health issues may receive.

Endnotes

1 President's Budget for FY 2006: Department of Health and Human Services, pp. 127–149 (Budget).

2 *See* "Report to Congress: Medicare Payment Policy," Medicare Payment Advisory Commission, p. 40 (March 2005).

3 *Budget Facts*, Medicare Fact Sheet, p. 4 (Feb. 7, 2005).

4 *See* 42 U.S.C. § 1395ww(d)(5)(J)(iv)(II).

5 President's Budget Initiatives to Expand Access to Health Insurance and Health Care, p. 1 (Feb. 4, 2005).

6 *See Id.*

7 "Report to Congress: Physician-Owned Specialty Hospitals," Medicare Payment Advisory Commission, p. 35 (March 2005) (Specialty Hospital Report).

8 *Id.*

9 Specialty Hospital Report, p. 36.

10 *Id.*

11 *Id.*

12 Specialty Hospital Report, p. 40.

13 Specialty Hospital Report, p. 39.

14 Specialty Hospital Report, p. 40.

15 Specialty Hospital Report, p. 41.

16 *Id.*

17 *See* Specialty Hospital Report, pp.41-42.

18 Specialty Hospital Report, p. 44.

The Reimbursement List Serve Works: Two ASCs Operating Out of the Same Space?

The Regulatioin, Accreditation, and Payment Practice Group continues to find a number of lively and engaging topics being shared among the listserve members.

Case in point, on December 1, 2004, the Healthcare Reimbursement Listserve posted the following anonymous question:

> Are you aware of any situations where two distinct entities (with separate tax ID numbers) are operating separately certified Ambulatory Surgery Centers (ASCs) out of the same location (e.g., entity one is operating the ASC on Monday/Wednesday/Friday and entity two is operating the ASC on Tuesday/Thursday, with each entity billing using its own Medicare number)?
> Have you been involved in any situations where CMS or the local Carrier disallowed this type of arrangement? Are you aware of any published regulations or guidance from CMS or Local Carriers allowing or disallowing this type of arrangement?

After a number of interesting responses back and forth, an anonymous source inside CMS directed listserve members to a June 12, 2003 memorandum from Steven Pelovitz to the State Survey and Certification Regional Office Management and State Survey Agency Directors. *See* www.cms.hhs.gov/medicaid/survey-cert/sc0322.pdf (Ref: S&C-03-22).

In that memo, Mr. Pelovitz responds to the question of whether an ASC and an Independent Diagnostic Testing Facility (IDTF) may work out of a common space, but operate at different times in that space. At the outset, Mr. Pelovitz notes that current Medicare regulations at 42 C.F.R. § 416.2 do not allow an ASC and another entity to mix functions and operations in a common space during concurrent or overlapping hours of operations. He goes on to note that two facilities may operate out of the same space so long as they operated at different times within that space. Mr. Pelovitz goes on to even expand this interpretation to permit ASC and IDTF entities to operate *at the same time* in certain circumstances:

> When there is a need for imaging services during the course of a procedure in progress at an ASC, the IDTF sharing the space with the ASC (but at different times), may conduct the required service outside of its normal business hours, as needed, and receive Medicare payment for those services. In this situation, our regulations and policy allow the IDTF to bill and receive Medicare payment for imaging and guidance services (such as angiography, venography, fluoroscopy, and ultrasonic needle guidance) *that are reasonable and necessary and directly related to the performance of a surgical procedure and furnished in conjunction with a surgical* procedure despite being conducted during the ASC's designated hours.

S&C-03-22 (emphasis in original). A number of listserve members joined in the discussion reminding all that, while CMS may in theory, permit two entities to operate out of the same space from a certification perspective, state law must be carefully examined to determine whether this is permissible from either a licensure and/or certificate of need perspective.

If you have reimbursement questions, please continue to use the reimbursement listserve—you never know when CMS may be watching (and responding). Anonymous questions may be directed to our listserve moderator, Barry Alexander, at barry.alexander@nelsonmullins.com.

Year in Review

I. Case Summaries

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Fifth Circuit Finds Disputed, M+C Subcontracted ESRD Services Are Not Claims under the Medicare Act; Remands to State Court

Humana, a Texas HMO, contracted with Centers for Medicare and Medicaid Services (CMS) to provide health services to Medicare+Choice (M+C) beneficiaries under Part C of the Medicare program. Humana subcontracted with RenCare for End-Stage Renal Disease (ESRD) services for both M+C beneficiaries and other HMO enrollees. The amount of reimbursement paid by Humana to RenCare was disputed, and RenCare sued Humana in Texas state court. Humana moved for removal, arguing that the claims were preempted by the Medicare Act and thus belonged in federal court. The Federal District Court retained jurisdiction over the case as it related to M+C beneficiaries only and later dismissed for RenCare's failure to exhaust administrative remedies. RenCare appealed. The Fifth Circuit found that these were not Medicare claims, as the federal government had transferred its risk of loss under Medicare Part C to Humana. Accordingly, RenCare's claims were not subject to the M+C administrative appeals process. The claims were remanded to state court. *RenCare, LTD v. Humana Health Plans of Texas*, dba Human Health Plan of San Antonio; Humana HMO of Texas, Inc., No. 04-50087 (5th Cir. Dec. 30, 2004).

CMS Administrator Reverses PRRB Allowance of Provider Bad Debt Claims on Uncollectable Cost Sharing Amounts Outside the ESRD Facility Composite Rate

The Intermediary appealed the Production Readiness Review Board's (PRRB) reversal of its disallowance of provider bad debt claims on uncollectable deductible and coinsurance amounts for items and services not included in the ESRD composite rate. The PRRB had found that Medicare reimbursement for bad debts related to all covered ESRD items and services, whether they related to the composite rate or were separately billed. PRRB Dec. No. 2005-D2. The Center for Medicare Management and the Intermediary argued that payment for bad debts has never applied to services paid on a fee schedule, flat fee or charge methodology, because Medicare does not share proportionately in a provider's incurred costs under such methodologies. They argued that bad debt policy applies only to cost reimbursement or cost-based prospective payment systems. The providers argued that the regulation in effect during relevant cost reporting periods stated that ESRD bad debt expenses need only relate to the composite rate services in order to be reimbursable. The CMS Administrator reversed the PRRB. *Dialysis Clinic 94 Bad Debt Expense Group v. Blue Cross Blue Shield Association/Blue Cross Blue Shield of Georgia Intermediary*, CMS Administrator Dec. (Jan. 13, 2005).

HHA Excess Travel Costs Are Not Atypical Services Supporting Exception to Cost Limits

A home health agency's (HHA) request for exception to per visit cost limits for each of three fiscal years was denied. The basis for the request was excess travel costs incurred to do the remote location of the beneficiaries' residences. The exception could be granted only upon a finding that the actual cost of "items or services" exceeded the applicable limit due to the atypical nature of the items and services. The majority of the PRRB found that "items and services" have to do with the actual clinical treatment of patients in accordance with orders given by the patient's physician or authorized healthcare provider. Travel expenses did not qualify. *Flagstaff Medical Center and Northern Arizona Homecare-Flagstaff v. Blue Cross Blue Shield Association/Unites Government Services, LLC-CA/Blue Cross Blue Shield of Arizona*, 2005-D11 (Dec. 17, 2004).

II. Accreditation Update

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JCAHO Proposes Collection of Race, Ethnicity and Language Data

The Joint Commission on Accreditation of Health Care Organizations (JCAHO) proposed in December 2004 a new standard to require accredited managed care organizations and integrated delivery systems to collect information on patients' race, ethnicity, and primary language. JCAHO believes that collecting this information will allow managed care plans to better understand the characteristics of the populations they serve and to provide safer and higher quality healthcare.

JCAHO Proposes A Reform of Medical Liability System

JCAHO is urging reform of the medical liability system in a public policy white paper entitled *Health Care at the Crossroads: Strategies for Improving the Medical Liability System and Preventing Patient Injury*. JCAHO's report emphasizes patient safety and medical injury prevention by health care providers and practitioners along with open communication between patients and practitioners. JCAHO is also proposing the creation of an injury compensation system that is "patient-centered." JCAHO believes the current liability system fails "because it does not effectively deter negligence, truly offer corrective justice, or provide for compensation to those who have been injured through the care process."

Continued on page 14

Continued from page 13

III. Regulatory Update

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Final Rules

A. Medicare Prescription Drug Benefit; 70 Fed. Reg. 4194 (CMS-4068F), Jan. 28, 2005

This final rule implements the Medicare voluntary Prescription Drug Benefit Program, enacted as Section 101 of Title I of the 2003 MMA, which is slated to become available to beneficiaries beginning January 1, 2006. Coverage for the prescription drug benefit will be provided either by private prescription drug plans (PDPs), which will offer only prescription drug coverage, or through Medicare Advantage prescription drug plans (MA-PDs), which will offer prescription drug coverage that is integrated with the health care coverage provided to Medicare beneficiaries under Part C of Medicare. PDPs must offer a basic prescription drug benefit. MA-PDs must offer either a basic benefit or broader coverage for no additional cost. MA-PDs or PDPs may also offer supplemental benefits for an additional premium. All organizations offering drug plans will have flexibility in terms of benefit design, including the authority to establish a formulary to designate specific drugs that will be available, and the ability to have a cost-sharing structure other than the statutorily defined structure, subject to certain actuarial tests. Most Part D plans may also include supplemental drug coverage such that the total value of the coverage offered exceeds the value of basic prescription drug coverage. This final rule also provides for subsidy payments to sponsors of qualified retiree prescription drug plans to encourage retention of employer-sponsored benefits. It also provides for options for facilitating additional coverage through employer plans, MA-PD plans and high-option PDPs, and through charity organizations and State pharmaceutical assistance programs. The final regulations are codified in 42 CFR Part 423.

B. Establishment of the Medicare Advantage Program; 70 Fed. Reg. 4588 (CMS-4069-F), Jan. 28, 2005

This final rule implements Title II of the 2003 MMA by establishing and regulating the Medicare Advantage (MA) program. The MA program replaces the Medicare+Choice (M+C) program established under Part C of title XVIII of the Act. While retaining most key features of the M+C program, the MA program attempts to broadly reform and expand the availability of private health plan options to Medicare beneficiaries. According to CMS, the MA program is designed to: provide for regional plans that may make private plan options available to more beneficiaries, especially those in rural areas, and expand the number and type of plans provided, so that beneficiaries can choose from Health Maintenance Organizations (HMOs), Preferred Provider Organization (PPO) plans, Fee-for-Service (FFS) plans, and Medical Savings Account (MSA) plans, if available where the beneficiary lives.

Beginning in 2006, payments for local and regional MA plans will be based on competitive bids rather than administered pricing. MA organizations will submit an annual aggregate bid amount for each MA plan. An aggregate plan bid is based upon the MA organization's determination of expected costs in the plan's service area for the national average beneficiary for providing non-drug benefits (that is, original Medicare (Part A and Part B) benefits), Part D basic prescription drugs, and supplemental benefits if any (including reductions in cost sharing).

These regulations are effective March 22, 2005 except for certain changes that will become effective on January 1, 2006. The final regulations are codified in 42 CFR Part 422.

C. Durable Medical Equipment Regional Carrier Service Areas and Related Matters; 70 Fed. Reg. 9232 (CMS-1219-F), Feb. 25, 2005

This final rule provides a mechanism for CMS to expeditiously make certain changes to the durable medical equipment regional carrier (DMERC) contracting process through issuance of a Federal Register notice without notice and comment rulemaking. CMS can: (1) change the geographical boundaries served by the regional contractors that process DME claims; (2) make other minor changes in the contract administration of the DMERCs; (3) change the method for increasing or decreasing the number of DMERCs; (4) change the method for changing the boundaries of DMERCs based on criteria other than the boundaries of the Common Working File sectors; and (5) award new contractors to perform statistical analysis or maintain the national supplier clearinghouse. CMS did not alter the criteria and factors that it uses in awarding contracts. This rule is effective March 28, 2005.

Notices

A. Monthly Payment Amounts for Oxygen and Oxygen Equipment for 2005, in Accordance with Section 302(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; CMS-1299-N, Feb. 4, 2005

This notice discusses a reduction in the 2005 monthly payment amounts for oxygen and oxygen equipment based on the percentage difference between Medicare's 2002 monthly payment amounts for each State and the median 2002 Federal Employee Health Benefit plan price reported by the Office of Inspector General. This reduction is required by section 302(c) of the MMA.

B. Procedures for Maintaining Code Lists in the Negotiated National Coverage Determinations for Clinical Diagnostic Laboratory Services; CMS-3119-FN, Feb. 25, 2005

This notice finalizes the procedures proposed in the Federal Register on December 24, 2003 (68 FR 74607). It establishes procedures for maintaining the lists of codes that were included in the national coverage determinations (NCDs) that were announced in

an addendum to the final rule published in the Federal Register on November 23, 2001 (66 FR 58788). The final notice also sets forth the circumstances in which a laboratory is permitted to use the date a specimen was retrieved from storage for testing as the date of service instead of the date of collection.

C. Changes in Geographical Boundaries of Durable Medical Equipment Regional Service Areas; CMS-1219-N, Feb. 25, 2005

This notice announces changes to the geographical boundaries of the four Durable Medical Equipment (DME) service areas applicable to future awards of the Medicare Administrative Contracts (MACs). CMS identifies which States and territories are assigned to each of the four DME service areas, and includes the factors and criteria that it used to change the geographical boundaries.

Proposed Rules

Proposed Rules were issued on the following topics:

1. Prospective Payment System for Long-Term Care Hospitals: Proposed Annual Payment Rate Updates, Policy Changes, and Clarification; CMS-1483-P, Feb. 3, 2005.
2. Conditions for Coverage for End Stage Renal Disease Facilities; CMS-3818-P, Feb. 4, 2005.
3. Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants; CMS-3835-P, Feb. 4, 2005.
4. Conditions for Coverage for Organ Procurement Organizations (OPOs); CMS-3064-P, Feb. 4, 2005.
5. E-Prescribing and the Prescription Drug Program; CMS-0011-P, Feb. 4, 2005.

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Spring (May) 2005 Volume 8 Issue 2