THE ACADEMY OF MEDICINE OF CLEVELAND & NORTHERN OHIO (AMCNO)

PRACTICE MANAGEMENT MATTERS

Fall 2007

Medicare Update

Also Inside this Issue: AMCNO Solving the Third Party Payor Puzzle Seminar flyer – sign up today

AMCNO responds to CMS Proposed Rule – Physician payment and GPCI calculation at issue

On behalf of our membership, the AMCNO submitted comments to the Centers for Medicare and Medicaid Services (CMS) relative to the issue of the impending Medicare payment cuts for physicians. In addition, the AMCNO sent strong comments to CMS regarding the items contained in the proposed rule relative to the geographic practice cost indices (GPCI) utilized by Medicare.

The Medicare physician fee schedule adjusts physician fees for area differences in physicians' costs of operating a private medical practice. Three separate indices, known as geographic practice cost indices (GPCI) raise or lower Medicare fees in an area, depending on whether the area's physician practice costs are above or below the national average. These GPCIs adjust physician fees for variations in physicians' costs of providing care in different geographic areas. The three GPCIs correspond to the three components of a Medicare fee: physician work, practice expense, and malpractice expense.

At this time, CMS uses 89 physician payment localities among which fees are adjusted. CMS recognizes that changing demographics and local economic conditions may lead to increased variations in practice costs in certain payment locality boundaries. Currently, the state of Ohio is designated as a statewide locality. This designation was made with the support of the state medical association more than ten years ago and over the strong objections of the AMCNO. The AMCNO objected due to the fact that a change to a statewide locality would impact payments to physicians in Northern Ohio since a statewide locality in Ohio clearly would not accurately account for the variations in practice costs in certain payment localities. As the regional organization representing physicians in Northern Ohio, the AMCNO continues to advocate for a change in the payment localities utilized in Ohio. A copy of our letter to CMS has been sent to the Government Accounting Office and the Department of Health and Human Services. A copy of our letter may be viewed on our website at www.amcnoma.org - any questions regarding this issue may be forward to E. Biddlestone at the AMCNO at 216-520-1000, ext. 100.

Guide to Medicare Preventive Services Now Available

The 2nd Edition of The Guide to Medicare Preventive Services for Physicians, Providers, Suppliers and Other Health Care Professionals can be attained in a downloadable format from the Centers for Medicare and Medicaid Services (CMS.) This guide provides fee-for-service health care providers and suppliers with coverage, coding, billing and reimbursement information for preventive services and screenings covered by Medicare. The guide may be accessed at: http://www.cms.hhs.gov/MLNProducts/downloads/mps_guide_web-061305.pdf

Physicians may edit and save changes to Medicare enrollment forms electronically

Doctors who download Medicare enrollment forms (CMS-855 series) from the Centers for Medicare & Medicaid Services (CMS) Web site now have the ability to save changes electronically. Physicians who need to submit an enrollment form or changes to their enrollment information can input their enrollment information electronically by keying in their information, saving the changes to their computer and then printing them. For more information go to: **http://www.cms.hhs.gov/MedicareProviderSupEnroll/03_EnrollmentApplications.asp#TopOfPage**

Electronic Funds Transfer (EFT)

Electronic Funds Transfer (EFT) allows your financial institution to deposit your Medicare payments into accounts designated by you. There is no charge by Medicare for this service. These deposits will appear on your bank statements. Medicare does not use EFT to withdraw money from your account. EFT will: Allow quicker receipt of your payments, avoid the possibility of your checks being lost or delayed in the mail, increase security for your office (paper checks can be stolen), and allow savings in Medicare dollars for paper, printing, and postage. If you are interested in receiving your payments electronically, you will need to complete an EFT application form. In addition to the application, you must include a voided check. This will ensure that they have the correct American Banking Association (ABA) number. Your application cannot be processed without the voided check. To obtain the application, go to http://www.PalmettoGBA.com/boh and then click on forms. The application is under Electronic Funds Transfer (EFT) Registration Form.

NPI Crosswalk Information

Effective October 8, 2007, PalmettoGBA began editing the NPI/legacy ID combinations for validity against the NPI crosswalk file. Where a match cannot be located on the crosswalk, claims will be rejected or returned to the provider. When the claim is returned, a provider should first verify that the correct NPI was submitted. If correct, you will need to verify that your legacy identifier (PIN or NSC) number corresponds with the information on file with the National Plan and Provider Enumeration System (NPPES). This data may be checked at https://nppes.cms.hhs.gov

If the NPPES information is correct and you have included and matched ALL Medicare legacy identifiers with a corresponding NPI in NPPES, but you are experiencing provider identifier problems you may need to submit a Medicare enrollment application (CMS-855). If necessary, contact the PalmettaGBA offices at 1-866-308-5439 for more information.

Medicare Starting to Reject Claims with NPI Discrepancies

Physicians and their staff should be aware that Medicare may reject claims if they cannot match the physician's PIN to the physician's correct National Provider Identifier (NPI). Claims processed by Medicare carriers before Sept. 4 were going through the Medicare computer systems even if an appropriate match between the physician's NPI number and their old legacy billing number(s) couldn't be made. However, as of Sept. 4, Medicare has started to review the edits that previously allowed these claims to process. Physicians should check with their billing office to determine if any error codes have been returned by Medicare. These codes could indicate an NPI mismatch in the Medicare system. Physicians who use a clearinghouse should check to ensure that the NPI error reason code or similar error reason codes are not being stripped off of their claims.

NPPES Data & New Data Dissemination Training Module Now Available

The NPI Registry and the downloadable file are now available. To view the Registry, visit https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome.do on the Web. The downloadable file is available at http://nppesdata.cms.hhs.gov/cms_NPI_files.html on the Web. Additionally, the final module in the NPI Training Package is now available. Module 4, Data Dissemination, is now available at http://www.cms.hhs.gov/NationalProvIdentStand/Downloads/NPI_Module4_Data_Dissemination.pdf on the CMS Web site. This module describes the policy by which CMS will make certain NPPES data available, as well as the data CMS is disclosing. As always, more information and education on the NPI can be found through the CMS NPI page www.cms.hhs.gov/NationalProvIdentStand on the CMS website. Providers can apply for an NPI online at https://nppes.cms.hhs.gov or can call the NPI enumerator to request a paper application at 1-800-465-3203.

The CMS discontinued assigning UPINs on June 29, 2007, but CMS will maintain its UPIN public "look-up" functionality and registry website http://www.upinregistry.com/ through May 23, 2008.

2008 Vaccine Administrations

Effective January 1, 2008 physicians can no longer bill Medicare Part B for the administration of Medicare Part D-covered vaccines, using the special G HCPCS code (G0377.) Instead, you will need to bill the patient for the vaccine and its administration, and the patient will need to submit the claim to their Part D plan for reimbursement. THIS GUIDANCE DOES NOT AFFECT PART B COVERED VACCINES. To view a document on this reimbursement policy go to http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0727.pdf or call 1-877-567-9232 for more information.

Modifier Look-Up Tool Now Available
Questions about what modifier to use on a claim? PalmettaGBA has developed a new tool on their website that contains all the information you need to document and correctly submit modifiers. The information is revised on a regular basis. To access the Modifier Lookup tool go to http://www.PalmettoGBA.com/boh

Medicaid

Usage of Tamper Proof Rx Pads Delayed for Six Months
Strong advocacy by the AMCNO and other organizations, in particular the Ohio Pharmacy Association, helped secure a six-month delay of a federal requirement that handwritten Medicaid prescriptions must be written on tamper-resistant prescription pads. Efforts included a letter, signed by the AMCNO president to Congressional representatives urging the passage of legislation to delay the mandate, which originally was to have taken effect Oct. 1. The new deadline for usage of the tamper-resistant drugs pads is April 1, 2008.

Sens. Sherrod Brown, D-Ohio, and George V. Voinovich, R-Ohio sponsored this measure in the Senate and Rep. Charlie Wilson, D-Ohio sponsored the bill in the House. The bill allows six more months before prescriptions for patients on Medicaid must be tamper proof. The Ohio lawmakers say they hope the six-month delay will give doctors and pharmacists time to learn how to comply with the law without it posing problems for them or their patients.

The AMCNO has been monitoring the development of this issue and how it could impact a physician practice. Physician offices and staff should be aware that even though there is a six-month delay now in effect, offices should start now to get acquainted with what the new rule will require once implemented. Listed below is a short synopsis of what physicians and their staff may expect once this requirement is in full effect on April 1, 2008:

Overview of tamper resistant prescription pad law (to become effective in six months)
In order for Medicaid outpatient drugs to be reimbursable by the federal government, all written, non-electronic prescriptions must be executed on tamper-resistant pads. To be considered tamper resistant a prescription pad must contain at least one of the following:

- one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;
- one or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber; or
- one or more industry-recognized features designed to present the use of counterfeit prescription forms.

In addition, at a point one year after the implementation date, in order for prescriptions pads to be considered tamper resistant, a prescription pad must contain all three of the foregoing characteristics.

The requirement, once implemented, will apply to:
- All written prescriptions presented at the pharmacy on or after the published implementation date regardless of when the prescription was written;
- Written prescriptions for all outpatient drugs, including controlled, non-controlled, and over-the-counter drugs;
- Written prescriptions for drugs provided in a long-term care facility;
- Written prescriptions when Medicaid pays any part of the claim, including when Medicaid is not the primary payer, and
- Written prescriptions billed to Medicaid after the date of service due to retroactive eligibility.

The requirement, once implemented, DOES NOT apply to:
- Orders for medications administered in a provider setting (e.g., physician office or hospital outpatient or emergency department) and billed by the administering provider.
- Refills of written prescriptions presented at a pharmacy before the implementation date;
- Electronic, faxed or telephoned prescriptions; and

- Prescriptions for which payment will be made by a Medicaid managed care entity (i.e., this requirement applies only to prescriptions written for patients who receive a monthly paper Ohio Medicaid card, not to prescriptions written for patients enrolled in a Medicaid managed health care organization)
- Physician offices are NOT exempt
- In addition, prescriptions will be covered if the physician provides the pharmacy with a verbal, faxed, electronic, or tamper-resistant written prescription within 72 hours of the date the prescription was filled.

Physicians interested in obtaining compliant prescription pads prior to the revised implementation date may want to contact the following vendors for more information:

- MediScripts can provide pads for individual physicians in all specialties, except surgery, where special group requirements apply. They do NOT provide individual pads for APNs or PAs. Call them at 1-800-387-3636 for more information.
- For those physicians who are used to printing their own prescriptions and prefer customized, non-commercial pads, another possible source is Rx Pads, Inc. This company has the tamper proof "security" pads that meet all the standards and offer pads in varying quantities with greater discounts the more you order. For example, they charge $33.95 plus shipping for 10 pads. For more information check their website at www.rxpads.com/2007/Index.aspx or call 800-307-7717.
- ScriptShield is offering a 10% discount for its HologramRx scripts and 5% off of National RxSecurity script prices for pads ordered between now and the end of the year. To receive an order form, call either HologramRx at 1-866-356-1050 or 1-800-510-1050. or visit their website at www.scriptshield.com or www.nationalrx.net.

The AMCNO will continue to provide our members with input on this issue as information becomes available.

Prompt Payment Requirements for Medicaid Managed Care Plans (MCPs)

Under the Ohio Department of Job and Family Services MCP Provider Agreement, MCPs must pay 90% of all submitted clean claims within 30 days of the date of receipt and 99% of clean claims within 90 days of receipt. These rules apply unless the MCP and provider have established an alternative schedule that is specific in their contract. The Ohio Department of Insurance (ODI) prompt payment requirements do not apply to Medicaid MCPs. The Center for Medicare and Medicaid Services (CMS) clarified that state requirements may not supersede federal regulations, therefore, ODJFS reviews and monitors MCPs for compliance with the federal requirements.

MCPs submit prompt payment reports to the ODJFS semi-annually and ODJFS selects 2-3 MCPs each year to be audited by an external ODJFS contractor to verify the reports. If an MCP does not meet federal requirements they are assessed penalties. Questions on this policy may be submitted via email to bmhc@odjfs.state.oh.us or call 1-614-466-4693. In addition, if AMCNO members are experiencing prompt pay problems with MCPs we would like to hear about it. Please see the form at the end of this update for more information on how to send this information to the AMCNO.

AMCNO physician leadership meets with Director Jones-Kelley from the Ohio Department of Job and Family Services (ODJFS)

The AMCNO discussion with the Director from ODJFS was centered on the Medicaid Managed Care Plans (MCPs), how the plans were implemented, how hospitals and physicians contracted to enroll in the plan, and how physicians in Northern Ohio could prepare for the next rollout of the program this fall. The AMCNO also suggested that the ODJFS consider surveying the Medicaid recipients in the state to ascertain their level of understanding of the program, whether or not they are able to see their physician of choice, what information they get from the plans, and their level of understanding of the enrollment in the program. The AMCNO has asked for an appointment to the ODJFS Ohio Medical Care Advisory Committee for Medicaid so that we may provide our input on issues of importance to our members relative to MCPs and other Medicaid programs.

Third Party

UnitedHealthCare (UHC) Rolls Out Advance Notification Program

UnitedHealthCare recently sent out correspondence to physicians and hospitals concerning UHC's advance notification program. AMCNO leadership has discussed this program with the medical director of UHC and have learned that, consistent with current UHC practice physicians, health care professionals and non-facility providers rendering services are still

required to provide notification for all admissions. However, in order to promote administrative simplification, as of December 3, 2007, UHC is reducing the number of inpatient admissions that would require advance notification. Failure to notify for specific elective procedures will impact reimbursement.

Physicians are responsible for advance notification for in-patient services involving orthopaedic surgeries (spinal surgeries, total knee replacements and total hip replacements); transplants; reconstructive/potentially cosmetic procedures, and bariatric surgeries. The new rules for these specific in patient services will require advance notification at least 5 business days prior to planned admissions (or as soon as the admission is scheduled if it is scheduled less than 5 business days in advance). Advance notification from the physician has to occur before the patient is admitted to the hospital.

Reimbursement reductions will occur only if the advance notification is not received. Reimbursement reductions will only impact the party who fails to meet their specific obligation under the program (i.e. physicians, health care professionals, non-facility providers and hospitals will no longer be impacted by another party's failure to provide required notification). However if a physician does not meet the obligations for advance notification when billing for a service on the advance notification list they will be subject to reductions off the contracted rate BEFORE member benefits.

Hospitals will be required to notify UHC within 24 hours of the patient's admission to the hospital. UHC will have 24-hour availability for hospital contacts. Reductions for late admission notification will apply equally to hospitals of ALL contracted types. If the hospital fails to provide admission notification or admission notification is received more than 72 hours after admission UHC will apply a 50% reduction off the contracted rate for the entire admission before enrollee benefits (this applies only to hospitals related to any inpatient admission). If the hospital provides a late admission notification (i.e. received more than 24 hours but within 72 hours after admission) they will be subject to a 50% reduction based on the computed average of the daily contracted payment rate for the days preceding notification (applies only to hospitals related to any inpatient admissions.) Additional information may be obtained at the UHC website at www.uhc.com.

UnitedHealthCare Premium Designation Letters Mailed to Physician Offices

Letters went out in September informing physicians of their Premium Designation status with UHC. There is a six-week "reconsideration period" after receipt of the letters. Physicians will have from 9/7/07 to 10/31/07 to provide self-reported, additional information on patient cases. Physicians that meet the quality and efficiency guidelines will receive a two-star designation, and physicians that meet the quality guidelines will receive a one star designation. There could be several reasons why a physician would not meet either of the guidelines. There may be no record with UHC that they are board certified, or it could be they did not have a sufficient number of claim volume. If a physician does not meet either of the guidelines, the physician may go to the UHC portal and check their cases to see if they can provide additional data. The physicians who receive only the quality rating but not the efficiency rating may also want to check and verify their data.

UnitedHealthCare launches online claim estimator

Physicians who work with UHC now have access to a new online claim-estimating tool that makes confirming eligibility and anticipating costs associated with medical care easier. Physicians can determine in advance of a patient's office visit whether the individual is covered for a procedure and the estimated cost of the service. The cost estimate includes how much the patient will owe and how much the physician is likely to be reimbursed. The Claim Estimator is available to doctors now at UHC's dedicated physician Web site at www.unitedhealthcareonline.com

Medical Mutual of Ohio (MMO) NPI Implementation

After October 1, 2007, for an 837 Claims Transaction, if a provider submits a claim with the company 12-digit legacy ID number only, MMO will reject the claim. However, if a provider submits a claim with an NPI AND the Company 12-digit legacy ID number, they will accept the claim. Claims submitted using only the NPI are accepted as well.

When submitting NPIs in combination with the legacy ID, enter NPI numbers in Box 33a (LOOP 201oAA NM1 Segment in the 837 electronic claims transaction) and the legacy ID number in Box 33b. Should the rendering provider's NPI differ from the NPI in Box 33a, the rendering provider's NPI should be entered in Box 24j, which is LOOP 2310B in the 837 electronic claims transaction. When submitting claims with NPI only, enter NPI numbers in Box 33a (LOOP 2010AA NM1 Segment in the 837 electronic claims transaction). Should the rendering provider's NPI differ from the NPI in Box 33a utilize the same instructions as above.

Physicians may register their NPI with MMO. NPI numbers can be submitted by completing a Provider Information Form (PIF). The PIF can be found online in the Provider section at www.medmutual.com.

LabCorp Network Participation with Medical Mutual of Ohio Ends

As of September 1, 2007, Laboratory Corporation of American (LabCorp) no longer participates in Medical Mutual or Consumer Life networks. All LabCorp services, including draw sites and analysis, were affected. At this time, a member referred to a LabCorp facility will be subject to out-of-network sanctions and non-network benefits, if any, will be applied. Additionally, members may incur higher out-of-pocket expenses. MMO continues to contract with other national and local reference and specialty labs, such as Quest Diagnostics and its affiliates LabOne and CompuNet. To view a list of network providers go to www.medmutual.com.

NEWS YOU CAN USE

Protected Health Information – HHS clarifies medical privacy data

There have been questions recently about the privacy rules and regulations. The Centers for Medicare and Medicaid Services and the Dept. of Health and Human Services (HHS) want to be sure there is a clear understanding of these issues. Information has been posted to ensure that healthcare providers are aware of the helpful guidance and technical assistance materials the U.S. Department of Health and Human Services (HHS) has published to clarify the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The HHS complete listing of all HIPAA medical privacy resources is available at http://www.hhs.gov/ocr/hipaa/ on the HHS Web site. For a full list of educational materials, visit http://www.hhs.gov/ocr/hipaa/assist.html on the HHS Web site.

Retail Clinic Concept Continues to Raise Concerns

Recent acquisitions of retail health clinics by major pharmacy chains have sparked a debate concerning the ethics and economics of providing health care in the same location where drugs are dispensed. Recently, the American Medical Association (AMA), which emphasizes that it is not opposed to retail health clinics, has called for regulation of the clinics and new principles to make sure there are no unfair incentives for patients to choose care at the clinics over physician practices. Among the regulations sought by the AMA are investigations of the connection between retail clinics and pharmacy chains with an eye toward possible conflicts of interest and development of guidelines for model legislation that regulates the operation of store-based clinics. In addition, the AMA is questioning the concept of co-payment reductions and waivers, which some insurers are allowing retail clinics to offer. The AMA is of the opinion that these provide an unfair incentive for patients to choose a retail clinic for care versus physicians.

Of note is the fact that the AMCNO has had this issue on our radar screen for more than two years and physician leadership from the AMCNO have voiced concern to state agencies and the administrators of these clinics in Ohio. Among our concerns were the amount of supervision provided in these clinics by a licensed physician, privacy issues associated with HIPAA, self-referral implications; and public health concerns among others. AMCNO leadership believes that this concept further fragments health care and steers patients away from their medical home. The ‘convenience care’ offered is no substitute for the relationship between a patient and a primary care physician.

Responses received by the AMCNO board from our state regulators outlined that the clinics located in our state were operating under appropriate laws, however, if physicians in the community were to become aware of any healthcare related risks or lack of appropriate referrals, these matters should be referred to the appropriate state agency. The AMCNO board determined it would be prudent to have a policy in place regarding these store-based clinics as they continue to proliferate in our area and elsewhere.

A policy was adopted in September 2006 and published in the AMCNO publications. In brief, the AMCNO policy calls for store-based health clinics to have a well-defined and limited scope of clinical services, consistent with state scope of practice laws; must use standardized medical protocols derived from evidence-based practice guidelines; must establish arrangements by which their health care practitioners have direct access to and supervision by M.D.s/D.O.s consistent with Ohio law; have protocols for ensuring continuity of care with the practicing physicians within the local community; inclusive of encouraging patients to establish care with a primary care physician (PCP) to ensure continuity of care; clearly outline their policy on payment for services including types of health care coverage accepted by the clinic; inform patients in advance of the qualifications of the health care practitioners who are providing care, as well as the limitation in the types of illnesses that can be diagnosed and treated; and establish appropriate sanitation and hygienic guidelines and for these facilities to ensure the safety of patients.

At the September 2007 AMCNO board of directors meeting, another item was added to the above referenced policy which states: ***Health insurers and other third-party payors should be prohibited from waiving and/or lowering co-payments for patients that receive services at store-based health clinics.***

The AMCNO plans to review the model legislation developed by the AMA when it becomes available. In the interim, the AMCNO plans to continue to monitor the effects of store-based clinics on the healthcare community in Northern Ohio. The AMCNO would like our members to keep us apprised of how the presence of these clinics in our community has affected your patients and/or your practice. Please send in any comments/concerns you may have directly to our EVP/CEO, Ms. Elayne Biddlestone at ebiddlestone@amcnoma.org.

AMCNO Practice Management session planned for November

Now in its 22nd year, the AMCNO Solving the Third Party Payor Puzzle seminar is scheduled for November 15th at the AMCNO offices. This excellent program was the first of its kind in the state to bring together representatives from the various payors to provide input and comments on up to the minute changes and issues from the health insurance companies. Represented at this year's event will be representatives from PalmettoGBA (Medicare), the Ohio Department of Job and Family Services (Medicaid), Medical Mutual of Ohio, Anthem BC/BS and UnitedHealthCare. Registration fees for AMCNO members or their staff are only $50.00 per person. To obtain a copy of the registration form go to www.amcnoma.org - or see the last page of this update for a copy of the form.

AMCNO Discounted Classes Available at TriC

CUYAHOGA COMMUNITY COLLEGE

Discounted Continuing Education Classes for AMCNO Members and their Staff

Take advantage of local professional education on medical practice management issues!
Members and/or their staff will need an exclusive AMCNO course number to register and obtain the discount. For course numbers, call Linda Hale of AMC/NOMA at 216-520-1000, ext. 101, or e-mail lhale@amcnoma.org. Once you have obtained your discount course number, call Cuyahoga Community College to register at 216/987-3075.

Wednesday Seminar Series at Corporate College East; 4400 Richmond Road, Warrensville Heights, Ohio 44128

Sept. 12th	**Physician Quality Review Initiative (PQRI) Introduction $149**	**8am-12:15pm**
Sept. 26th	**Compliance and Advanced Chart Auditing $159**	**8am-12:15pm**
Oct. 10th	**Revenue Cycle Management Strategies $159**	**8am-12:15pm**
Oct. 10th	**Advanced ICD-9CM Coding Update $159**	**1:30pm-4:30pm**
Oct. 24th	**Appeals and Denials- Panel $99**	**11:30am-1:30pm**
Dec. 5th	**Instituting a Coding Compliance Program in the Practice $120**	**8am-11:00am**
Dec. 5th	**Advanced CPT Coding Updates $159**	**12:30-3:30pm**

Courses and Certifications:

Certified Medical Coder (CMC) by PMI: Wednesdays, Sept. 19-Oct. 24th. 8:30am-4:30pm. $899
AAPC Professional Medical Coding Curriculum (CPC-A): Evening Courses start in August- 6:00pm-9:00pm; Corporate College East and Westlake. $1650
CPC Certification Exam Review: Saturday, Dec. 1. 9:00am-2:45pm. $120
Medical Terminology/Anatomy and Physiology: day and evening courses; various times and locations. $216

Adapting to Changes in Physician Relationships with Hospitals and Industry

By Amy S. Leopard, Esq., Walter & Haverfield LLP

Physician relationships with hospitals, healthcare systems and others in the healthcare industry have been under intense scrutiny by federal regulators during the past year. The feds are revitalizing efforts to restrict the financial relationships physicians have with hospitals, device manufacturers and entities to which physicians make referrals. The Center for Medicare and Medicaid Services (CMS) has tweaked the Stark II physician self-referral rule and proposing extensive changes for the future. At the same time, the U.S. Department of Justice and the Health and Human Services (HHS) Office of Inspector General (OIG) recently executed consent agreements with orthopedic device manufacturers that will single-handedly restructure compensation relationships between these surgeons and device companies.

Physicians can expect increased emphasis on both the disclosure of these relationships as well as the documentation required to pass muster. Physicians and their affiliated organizations need to study and understand what CMS and the OIG consider to be either problematic or flat out prohibited and use this learning to inform both short- and long-term planning.

Immediate Stark Law changes -- Stark III

CMS published a new Stark rule in September that will take effect on December 4, 2007. The Stark law prohibits a physician referral to an entity for certain "designated health services" covered by Medicare if a financial relationship exists between the referring physician (or an immediate family member) and the entity unless the arrangement meets an exception. Thus, the following changes demand immediate analysis and action if non-compliance is identified.

Probably the biggest change CMS is implementing is what is referred to as the new “stand-in-the-shoes” rule. *Under this provision, financial arrangements between entities that bill Medicare and physician organizations such as group practices will now be deemed to create a financial relationship with each of the referring physicians in the group on the same terms as the arrangement with the physician organization itself*. By collapsing the physician into the financial relationship, this rule now regulates indirect financial relationships previously outside the purview of the Stark law and requires a specific exception, rather than the current more lenient approach. A grandfathering provision will allow certain existing arrangements to comply with the rules in effect on September 5, 2007.

What this means is that outside an employment relationship, almost all financial relationships with a referring physician, whether direct or indirect through a group practice, will require a writing in advance of any compensation being paid. This remarkable change occurred without much industry comment and without CMS thinking through possible unintended consequences of such a broad sweep. Indeed, this change may be a trap for the unwary, or at the minimum, require wholesale recordkeeping changes between entities that bill Medicare and their referring physicians.

On the other hand, another upcoming change helps parties involved in compensation arrangements when technical non-compliance issues arise, such as when parties properly enter an agreement that lapses without renewal and the physician continues to perform services without a written agreement. In such an instance, CMS will allow a six-month holdover period on the same terms and conditions. Thus, when payments should continue to be made at fair market value for legitimate services rendered, this provision will reduce the risk that the failure to execute a renewal document timely will subject the parties to liability.

Finally, CMS has liberalized the circumstances under which physician recruitment and retention payments can be made and the criteria for what constitutes an appropriate “relocation” to be eligible for hospital subsidizes. Of significant interest to group practices receiving hospital payments to assist with physician recruitment is CMS’ stated intention to expand the ability of practices to impose certain types of restrictive covenants, such as a non-compete, on a recruited physician if the restrictions are deemed to be reasonable. How this provision will be interpreted is anybody’s guess.

Stark IV: The Final Frontier?

Under proposed Stark regulations pitched this summer, CMS put forth for consideration several bold initiatives that would have far-reaching and dire consequences if adopted. These broad proposals range from increased restrictions on the types of ancillaries than can be provided within group practices to changes that would quash many current hospital-physician alignment initiatives.

For physician groups, CMS is seeking comment on the type and scope of services to diagnose and treat patients that a group practice may provide. CMS is concerned about the proliferation of expensive imaging technologies and other in-office ancillary services. The July notice seeks public comment on whether CMS should restrict groups from furnishing (1) ancillaries other than at the time of an office visit, (2) ancillaries provided through “turn key” arrangements, (3) physical therapy provided by independent therapists within the group, and (4) high-ticket items generally. CMS appears to be questioning any arrangement with outside suppliers construed as a markup of the professional or technical component.

CMS also proposes some other technical changes to expand the types of entities that are regulated by the Stark law to go beyond those entities which bill Medicare directly. This broad brush would expand the Stark law to directlyregulate entities not billing Medicare which are not currently regulated, including leasing companies and staffing companies owned by physicians.

CMS is considering a reversal in the course it took in 2001 when it outlined how leases and services could be provided either on a 'per-click' basis or 'under arrangements.' An 'under arrangements' alignment model is a structure under which referring physicians provide goods and services to a hospital directly, or through a joint venture with the hospital, and the hospital then bills Medicare for the services (e.g., imaging, outpatient services, cardiac cath labs). The CMS proposal considers whether the Stark rule should prohibit these arrangements. This area must be watched closely over the coming months and may cause transactions for services furnished 'under arrangements' to be restructured or postponed.

CMS also asked for comment on whether it should continue to allow equipment rentals to be based on a "per click" basis; i.e., lease payments based on a per-use or per-service fee. CMS's concern here is that physicians will be rewarded for each referral made for services covered by Medicare. CMS would strictly prohibit any lease payments from fluctuating on the basis of referrals or other business generated between the parties, *i.e.*, where the rental charges reflect services provided to patients referred by the lessor physician to the lessee even if the payment was at fair market value.

Another area in which CMS seeks comment is compensation to physicians and physician organizations involving percentage-based arrangements. CMS would change its current policy allowing percentage compensation methodologies that meet fair market value standards by prohibiting percentage-based compensation unless the formula is based only on revenues generated from services that the referring physician personally performs.

These proposals reveal an about-face from regulations that expressly permitted 'under arrangements' models and percentage and service-based payments even if the physician received a payment generated through a referral from the physician. If adopted, these proposals would entail restructuring of most leasing arrangements not based on a set, fixed in advance rental payment.

It is not altogether clear whether CMS will adopt these provisions or simply regulate them differently, and industry commentators certainly will provide policy and statutory authority contrary to the CMS proposals. Nonetheless, the fact that CMS is asking these questions reveals a change in course and at a minimum it can be anticipated that these types of arrangements will be subject to additional safeguards and stricter scrutiny. Stay tuned.

Orthopedic Settlement Agreements

While CMS tightens the Stark rule, the OIG has focused on device manufacturers and surgeons with whom the device companies have consulting relationships. In an area distinguished by a lack of hard and fast rules and nuances in industry views on how to appropriately manage and disclose conflicts of interest, stakeholders grappling with these issues have issued a wide range of guideposts for compliance. Many of these are voluntary industry compliance practices or institutional codes of conduct adopted within the past year.

Now, the Justice Department has announced that five companies comprising 95 percent of the U.S. market for hip and knee implants have agreed to resolve allegations that their compensation arrangements with orthopods violated the federal anti-kickback law. The anti-kickback law prohibits anyone from offering, paying, soliciting or receiving anything of value in return for (a) referring or arranging for the referral of patients to receive services covered by Medicare, Medicaid and TRICARE or state health care programs, and (b) purchasing, ordering, or arranging for the purchase or order of items covered under these programs.

The orthopedic companies must overhaul physician compensation practices and adopt ongoing compliance monitoring and auditing. Four of the companies (Biomet, DePuy, Smith & Nephew, and Zimmer) also paid significant fines and penalties and entered five-year corporate integrity agreements with the OIG. A fifth company, Stryker, entered a non-prosecution agreement requiring 18 months of monitoring based on its early cooperation. These agreements anticipate significant internal and external monitoring and reporting and periodic certification of compliance to the government.

Of particular interest are some of the terms and conditions in the deferred prosecution agreements. These agreements defer prosecution of criminal conspiracy charges under the anti-kickback statute for 18 months based upon compliance program initiatives and remedial actions. The agreements make mandatory the AdvaMed Code of Ethics on Interactions with Healthcare Professionals. Specific safeguards are required to be monitored by outside independent monitors. A required safeguard will be the preparation of a "needs assessment" by 2007 year-end to reflect expected consulting service needs in the areas of medical and clinical training, educational, and R&D areas. An advance budget for the total amount of payments made to consultants for consulting, honoraria, scholarships, gifts, contributions, donations, etc. must be approved by the outside monitor.

Once the need is set, it will be used as a basis for all physician hiring beyond January 1, 2008. Payments for all consulting agreements are limited to the fair market value hourly rate and cannot exceed $500 per hour for time expended. Anything not approved within the plan will require an independent fair market value analysis (e.g., if outside of certain ranges). Royalty payments for intellectual

property contributions will require an analysis of the physician's individual contributions and cannot be paid in advance or in anticipation of product sales.

All consulting agreements must be in writing and executed by numerous company officials. Product development and research agreements must be specifically approved by the head of R&D, whereas clinical service agreements (for clinical trials, clinical studies, etc.) must be specifically approved by the Clinical/Regulatory Vice President. The company President, General Counsel and Compliance Officer each must execute **all** consulting agreements. The physician must provide a summary of the services provided and the company must independently verify in writing that consulting services were actually rendered and the length of service. Except for data collection, travel and prep time, a company representative must be present.

Finally, the government has focused on the disclosure aspects of these types of arrangements. New consulting agreements and renewals will require physicians to disclose their engagement both to their patients as well as any affiliated hospitals. Likewise, the orthopedic companies must prominently feature on their websites the names of retained consultants and disclose payments within $25,000 increments. It is not entirely clear how these formalities will be implemented, but certainly the contracting process has now become complex, the planning process elaborate, and the financial terms transparent for the entire orthopedic industry.

Conclusion

Many of these changes will complicate, sometimes unnecessarily, legitimate and beneficial arrangements within the industry. As is always anticipated when CMS and the OIG begin to tinker with these rules, unintended consequences and unforeseen regulatory burdens often take months, if not years, to identify and resolve.

For the foreseeable future, one thing is clear -- the regulatory environment within which physicians have financial relationships and make referrals is undergoing a marked transformation. As Stark III rolls out by year end, it is a good time to review 2008 compensation arrangements and consider the effects of these rules to determine whether restructuring is necessary and what compliance documentation will be required to protect both the physician and the organizations with whom the physician has financial relationships.

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This article present general information regarding legal developments and does not constitute legal advice for a particular set of facts.

Practice Management

MATTERS

The Academy of Medicine of Cleveland & Northern Ohio can provide you information on topics from balance billing to managed care to terminating the physician/patient relationship. Whatever your question or concern, the Practice Management Department is available to address or investigate any issue left unresolved. See the form at the end of this update for information on how to send in a query regarding a insurance company or contact us at 216.520.1000/email concerns@amcnoma.org

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Lower Level Meeting Room B

COST: **AMCNO Members/staff - $50 per participant** **Non-Members - $100.00**

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