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CMS revises reimbursement determination appeal procedures

Various provisions governing Medicare Part A provider reimbursement determinations, appeals before the intermediary hearing officers and the Provider Reimbursement Review Board (PRRB), and CMS Administrator review of PRRB decisions will become effective August 21, 2008, under a *Final rule* published by CMS on May 23, 2008.

Cost reporting. Under amendments to 42 C.F.R. §§405.1811(a)(1) and 405.1835(a)(1), effective for cost reporting periods ending on or after December 31, 2008, providers will have more time to evaluate whether they wish to file a cost report item under protest and eliminate the transitional administrative burden for intermediaries. Providers filing cost report items under protest will be required to explain their dissatisfaction with the amount of Medicare payment for the specific items at issue by stating why Medicare payment is incorrect for each disputed item. The regulatory amendments allow a provider to explain why it is unable to determine whether payment is correct as a result of not having access to underlying information.

Common ownership or control. A new §405.1835(b)(4) has been added to require a provider under common ownership or control to furnish the name and address of its parent corporation and submit a statement that, to the best of the provider's knowledge, no other provider to which it is related by common ownership or control has pending a request for a PRRB hearing on any of the same issues contained in the provider's hearing request. If a pending appeal exists, the provider must submit the provider name and provider number, as well as the case number for the appeal.

Appeal period. The method for determining the beginning and end of a specific appeal period has been clarified by amended definitions for the "date of receipt" for any documents received by a reviewing entity, party, or interested nonparty. At this time, the Office of Hearings is not able to implement an electronic docket, but such a system may be implemented in the future.

Providers of services. Hospitals, critical access hospitals, skilled nursing facilities, comprehensive outpatient rehabilitation facilities, home health agencies, and hospice programs will be recognized as "providers of services" for Medicare Part A reimbursement determinations and appeals under the amended 45 C.F.R. §405.1801(b)(1). Rural health clinics and federally qualified health centers will be recognized as Medicare providers under §1878(j) of the Social Security Act, and end stage renal disease facilities will be recognized as providers under §1881(b)(2)(D). Any other entity recognized as a provider under the Act also will be recognized as a provider for purposes of reimbursement determinations and appeals.

Other changes. The *Final rule* also addresses changes to group appeals, expedited judicial review, administrator review, the Children's Health Graduate Medical Education Program, and information collection. ■

Final rule, 73 FR 30190, May 23, 2008, Health Care Compliance Reporter ¶700,067.

Wolters Kluwer Law & Business

CMS, FDA join forces to improve quality, safety of medical products

A *Final rule* issued by CMS and a white paper released by the Food and Drug Administration (FDA) "will complement each other to improve patient safety and the quality of medical care," according to HHS Secretary Michael Leavitt.

The FDA white paper describes plans for an electronic system that will enable the FDA to search claims and medical records data to identify possible post-market adverse events involving drugs and medical devices. The CMS regulation will allow federal agencies, including the FDA, as well as states and academic researchers, to use Medicare Part D claims data for research, program oversight and evaluation, care coordination, quality improvement, and performance measurement initiatives.

FDA Sentinel System. The new FDA white paper, entitled "The Sentinel Initiative—A National Strategy for Monitoring Medical Product Safety," describes the proposed Sentinel System and calls for private and government participation. The System will use data from sources maintained by the entities that agree to participate. By allowing the FDA to access these sources of health information, the Sentinel System would promote early detection of drug and device safety problems.

FDA Commissioner Andrew von Eschenbach, M.D. noted, "With the Sentinel System we will no longer have to wait years to see how a drug or medical device is affecting millions of people. The era of 'wait and see' is going to become the era of 'tell me right now.'" He continued, "By harnessing the world's most powerful information technologies, and by partnering with CMS, the [Veterans Administration] and [Department of Defense], and an array of private health care organizations, we will have the ability to monitor a product's performance in millions of patients in real time. The Sentinel System will give us an unprecedented ability to detect problems as they first begin to surface."

In a 2006 report, the Institute of Medicine (IOM) recommended creation of an "active surveillance system" as a way to improve on the safe use of drugs. The FDA Amendments Act of 2007 (Act) included provisions requiring the development of such a system. The proposed Sentinel System would satisfy both the IOM recommendation and the Act's mandate.

Access to CMS data. The Medicare Part D Claims Data Rule (73 FR 30663, May 28, 2008) will allow the FDA, CMS, and other stakeholders to access claims data on medications used by Medicare beneficiaries with prescription drug coverage under Part D. The Part D claims data will be linked to Medicare inpatient and outpatient claims information, including diagnoses, medical treatments, hospitalizations, and physician services. This linking capability "will provide the FDA, other agencies, and researchers with a powerful new tool to investigate potential drug safety problems and questions about outcomes," according to Leavitt.

CMS Acting Administrator Kerry Weems said, "There's a clear nexus between the data collected through Medicare's prescription drug program and the FDA's role in protecting the public from adverse events. The public health and safety benefits from this cooperative venture with the FDA will be substantial."

Weems noted that CMS' most recent survey of Medicare beneficiaries revealed that people with Medicare use, on average, twice as many medications in a year as do other Americans. He explained that "Medicare beneficiaries' high usage of medications, coupled with numerous chronic health conditions, puts this population segment at a higher risk of adverse drug events than other Americans and makes them the group most likely to see benefits from the FDA's new Sentinel initiative."

Leavitt predicted that "this initiative will tremendously increase the FDA's capacity to monitor the use of medical products on the market." He added, "We are moving from reactive dependence on voluntary reporting of safety concerns to proactive surveillance of medical products on the market. In addition, Medicare data on prescription drug use will be available to help government agencies and academic researchers improve the safety, quality, and efficiency of health care services." ■

HHS Press Release, May 22, 2008.

CCH Health Care Compliance Letter

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Medicare recovery process draws criticism from stakeholders

The current process governing Medicare's recovery audit contractors (RACs) is harmful to small providers, according to Rep. Charles Gonzalez (D-Tex.), Chairman of the House Committee on Small Business, Subcommittee on Regulations, Health Care, and Trade. Testifying at a May 14, 2008, Subcommittee hearing, Gonzales noted that RACs get a part of every overpayment they recover.

"These contingency fees...have led to aggressive and, in some cases, improper pursuit of recoveries," he said, adding that the system encourages auditors to focus on recovering overpayments to Medicare providers rather than on correcting all improper payments.

Timothy Hill, Director of CMS' Office of Financial Management, said the system will be improved when the program becomes permanent.

RAC demonstration project. The Medicare Modernization Act of 2003 included a provision directing HHS to conduct a three-year demonstration program using RACs to detect and correct improper payments, primarily from coding errors, in Parts A and B of the Medicare program.

The demonstration project was designed to determine whether the use of RACs would be a cost-effective method to ensure detection and correction of improper payments to Medicare providers and help protect the Medicare Trust Fund. Since its inception in 2005, the project has collected nearly $440 million in overpayments.

The demonstration began in March 2005 in the states with the highest Medicare expenditures: California, New York, and Florida. Arizona, Massachusetts, and South Carolina were included later. The three-year time frame for the pilot project ended in March 2008.

Under the demonstration project, Medicare contractors detected underpayments and overpayments in the Medicare program and corrected them by collecting the overpayments and reimbursing providers who were underpaid, Hill said. The demonstration corrected a total of more than $1 billion in improper payments, he said, noting that most overpayments were collected from inpatient hospitals.

The Tax Relief and Health Care Act of 2006 made the RAC program permanent and mandated nationwide expansion of the program by no later than January 1, 2010. CMS has begun the expansion process by initiating a full and open competition for four permanent RACs to perform audits nationwide.

Permanent RAC process. All permanent RACs will be required to employ a physician medical director and certified coding experts, Hill said. The permanent RACs will have to pay back their fees if they lose at any level of an appeal, he added. In addition, permanent RACs will be able to review claims in the current fiscal year and look back for improper payments for up to three years, Hill explained. "CMS will place a much greater emphasis on provider education and training as part of the RAC program," he noted.

Criticism of the process. Gonzalez criticized the RAC process, saying, "It is clear the contractors are almost exclusively focusing on correcting overpayments." He noted that of the $371 million in improper payments detected in 2007, 96 percent constituted overpayments collected from providers. Four percent involved underpayments reimbursed to providers. (*See* "RAC demonstration project nets big gains," *Health Care Compliance Letter*, Vol. 11, Issue 6, March 18, 2008). "It is hard to believe that this number represents the true proportion of underpayments," he said.

Dr. Karen Smith, a family physician and owner of a solo private practice in Raeford, North Carolina, testified on behalf of the American Academy of Family Physicians. She said that a RAC audit has left her practice financially drained. She explained that the unannounced audit disrupted care and led to a denial of claims for a number of patients that exceeded the actual number treated by her office. The RAC, which, according to Smith, acted in an aggressive manner, also cited a lack of documentation regarding documents that the practice had provided in electronic format. "The refusal of the [RAC] to recognize the presence of appropriate and pertinent documentation in our electronic health record is at best discouraging," Smith said. ■

CCH Washington Bureau, May 16, 2008.

On The Front Lines

How to conduct clinical trials in the EU and Eastern Europe: Overview and comparison with the U.S. system*

by Paul R. DeMuro, J.D., MBA and Andrea Jaeger-Lenz, J.D., Contributing Editors

The global clinical trials industry currently is estimated to be worth more than $10 billion. Considering the ever increasing demand for treatments of more illnesses and more sophisticated medicines, it is bound to grow considerably in the future. Yet, escalating domestic costs and difficulties in recruiting patients for certain types of studies have led U.S. pharmaceutical companies to look abroad more and more to conduct clinical trials. Thus, globalization of clinical trials is one of the most notable trends in current clinical research.

As the Western European countries have no considerable cost or patient enrollment advantages with respect to the U.S., over the past decade or so pharmaceutical companies have been attracted increasingly to the countries of Central and Eastern Europe (CEE). The advantages to placing clinical trials in this area are:

- availability of patients from largely treatment naive populations, due to lack of money and limited reimbursement;
- large population: CEE has a population of over 300 million; Russia and Ukraine have an additional 200 million inhabitants;
- centralized health care system with large, highly specialized hospitals;
- high quality investigational sites for many teaching hospitals; and
- low cost per completed case.

CEE, however, is not one homogeneous area. It consists of countries belonging to the European Union (EU) and former East Block countries (non-EU). With respect to the legal regime for clinical trials, the differentiation between EU and non-EU CEE countries is crucial because the EU Clinical Trials Directive[1] is in effect. The countries beyond the scope of the EU Clinical Trials Directive follow their own individual legal regimes. The CEE countries whose legislation and administration regarding clinical trials are modeled according to the EU Clinical Trial Directive are: Estonia, Latvia, Lithuania, Poland, Czech Republic, Slovakia, Hungary, Romania, Bulgaria, and Slovenia. The CEE countries to which the Directive does not apply are: Croatia, Bosnia Herzegovina, Serbia and Montenegro, Macedonia, Albania, Belorussia, Ukraine, Moldova, and Russia.

Overview of the EU clinical trials system

All interventional clinical trials are covered by the EU Clinical Trials Directive and require authorization by each Member State's regulatory body, such as the BfArM (Germany's Federal Institute for Drugs and Medical Devices). This authorization is required regardless of the medicinal product covered and regardless of the sponsor, whether industry, government, research council, charity, or university.

Key points of the EU clinical trials directive are:

- *Protection of clinical trial subjects.* The Directive pays special attention to the protection of clinical trial subjects and informed consent. There is a requirement to ensure that minors participating in the trial have received adequate information according to their capability and understanding.
- *Procedures for ethics committees.* The Directive defines the procedures for ethics committees, including a time limit for decisions. Responsibilities of the ethics committees are very broad and include providing an opinion on the relevance of the clinical trial and its design and protocol, the suitability of the investigator and supporting staff, etc. The ethics committees play a key role early on in the trial. A single opinion must be given from the ethics committee for both single and multicentric clinical trials to streamline the process.
- *Absolute deadlines for the assessment of clinical trial applications.* Both the regulatory body and the ethics committee have to approve of the clinical trial. The timeline for the assessment by both entities is 60 days. The 60-day timeline can be extended only if the trial involves certain medicinal products, such as gene therapy or somatic cell therapy (an additional 30 days), products that require external consultation (an additional 90 days) and xenogenic cell therapy (no time limit). If, during that timeframe, the regulatory body, ethics committee, or both require the sponsor to make changes to the design and protocol of the clinical trial or provide additional information, the sponsor has only one chance to get it right.
- *Exchange of information between the regulatory body, the sponsor, and the European Agency for the Evaluation of Medicinal Products (EMEA).* EMEA hosts a safety and information

database on clinical trials, called EudraCT. Any clinical trial taking place in the EU, as of its application early on, has to be recorded with all details in this database. This allows an exchange of information between all Member States, covering in particular safety alerts and refusals of authorization. It is not public and is only accessible to the regulatory authorities of the EU Member States.

- *Standards for Good Clinical Practices (GCP) and good manufacturing practices (GMP).* All manufacturers of investigational medicinal products (IMPs), including placebos and active comparator products, require a manufacturing license. All IMPs must be manufactured according to GMP. If the IMP is manufactured outside of the EU, it is the responsibility of the sponsor or its legal representative in the EU to ensure that the product has been manufactured according to GMP. To enable the regulatory body and the ethics committee to verify GCP and GMP compliance, the directive allows for on-site inspections.
- *Pharmacovigilance.* Unexpected serious adverse events (SAEs), if fatal or life-threatening, are to be reported within seven days after knowledge by the sponsor. All other suspected SAEs must be reported within 15 days of first knowledge by the sponsor. Sponsors are to keep detailed records of all SAEs, which have to be submitted to regulatory bodies and ethics committees.

Focus: Eastern Europe

The EU Clinical Trials Directive presents important upsides, such as a foreseeable and more or less uniform standard of the rules applying to clinical trials and their approval process and conduct. Yet, due to varying interpretations of certain terms in the Directive (such as sponsorship, legal representative, approval guidelines, or drug safety reporting guidelines), the implementation of the EU Clinical Trials Directive was not universally considered a success according to some reports.

Increasing costs for clinical trials in the EU. In the short term, costs for clinical trials have increased up to 85 percent in certain countries, leading to a decrease in clinical trial activities in a number of EU Member States, in particular certain Member States belonging to the CEE territory. For example, prior to 2004, Poland was reported to be a market leader within the CEE for clinical trials. This has changed. Lured by prospects of higher savings, clinical research has been moving further eastward and out of the EU territory.

Loss of competitive advantage for EU clinical trials. On the timeline, a number of newly admitted EU Member States belonging to the CEE region have lost their competitive advantage of speedy clinical trial approval. Thus, it is no surprise that Russia and Ukraine, with their substantial populations and not falling under the EU regime, are among the fastest growing clinical research areas of the world. What draws sponsors to those countries are:

- rapid study initiation (typically 10-15 weeks from document submission to enrollment of the first patient);
- academic centers and specialized hospitals for all therapeutic areas;
- Western medical technique processes; and
- high enrollment rates and drug naive patients in many therapeutic areas.

Risk management. Where there is light, there is bound to be shadow. Close risk management is crucial for the success of clinical trials in these countries. At the planning stage, assessing site suitability is crucial. It is wise to stay clear of inexperienced sites, sites experienced but overloaded with other studies, or sites that have English language problems.

Equipment and training. Equipment is also an important consideration. It is not uncommon to find sites without basics such as computers, E-mail, fax machines, freezers, or other usual amenities. Sponsors, therefore, should allocate additional expenses for equipment and study-specific training.

Standards and documentation. In the set-up phase, sponsors should make sure that they have a good knowledge of local requirements and timelines to submit documents in accordance with the laws of the various countries. While investigators may be good doctors, for the most part they will lack education in this respect. During the monitoring stage, data quality, adherence to protocol, adverse event reporting, adequate laboratory test evaluation, and filing appropriate drug accountability need to be supervised closely.

During the close-out phase, sponsors should make sure that standards don't slip and that documents are archived correctly. According to certain reports, trials conducted in Eastern Europe had about double the number of inadequately completed clinical records compared to trials conducted in Western Europe. Thus, it may be advisable to employ specialized clinical research organizations for clinical trials taking place in Eastern Europe.

Basic differences to U.S. system

There are a number of differences in regulatory requirements for clinical trials in the EU and the US, the most important of which relate to:

- regulatory document submission;
- protection of clinical trial subjects;
- IMP issues; and
- retention of essential clinical trial documents.

Regulatory document submission

With respect to the application procedure, for a multicentric trial taking place in several U.S. states, there is one competent regulatory authority, namely the Food and Drug Administration (FDA), with a single submission and a single authorization granted. A multicentric clinical trial in a number of EU Member States requires one submission of application to competent authority per Member State.

Submission of new protocol. In the U.S., a new protocol can be submitted as an amendment to the investigational

new drug application (IND) of the investigational product. The FDA reviews the initial IND within 30 days, but there is no official review time for subsequent amendments to the IND. In the EU, there must be a stand-alone submission to the competent authority for each protocol. The review timeframe generally is 60 days, with one opportunity for the competent authority to request further information, during which time the clock stops. If the competent authority does not find the response satisfactory, however, the application is considered rejected. So there is only one chance to get it right.

Amendments to the protocol. In the U.S., no official approval is required for an amendment to the protocol. In the EU, substantial amendments require approval by the competent authority prior to implementation. The timeframe for approval is 35 days.

Notification of study closure. At the end of a U.S. trial, a notification of study closure must be submitted to the FDA in an IND update, but no particular timeframe for submission of the notification is specified. In the EU, each competent authority must be notified of the closure of the trial in its territory, and ultimately closure of the trial overall. The closure notification is to be issued within 90 days of a termination.

Human subjects protection

Turning to the protection of clinical trial subjects in the EU, there is a detailed list of informed consent document (ICD) requirements, as follows. Any payments to clinical trial subjects must be disclosed. No incentives or financial inducements for participation of minors or incapacitated subjects in a trial are allowed. There are no provisions outlined for emergency consent. Additionally, some countries require insurance information to be included in the ICD. In the U.S., there are no requirements for insurance information in the ICD.

The European data protection directive applies to clinical trials in the EU. In the U.S., local sites are required to incorporate Health Insurance Portability and Accountability (HIPAA) regulations for privacy protection into consent clauses.

IMP issues

In the U.S., the IMP must satisfy U.S. GMP. In the EU, the IMP must be manufactured to a standard at least equivalent to EU GMP. An import authorization is required via application to the competent authority. In the U.S., labels on an IMP do not require an expiration date, which is not the case in the EU. Also, in the U.S., label samples are not required by the investigational review boards (IRBs), whereas the ethics committees in the EU may require such samples.

Retention of essential clinical trial documents

In the U.S., essential clinical trial documents must be stored for two years after the last approval or formal discontinuation of development of the product. In the EU, the sponsor and investigator shall retain the essential documents relating to a clinical trial for at least five years after its completion.

Other principles of GCP guidance

Clinical trials should be conducted in accordance with ethical principles originating with the Declaration of Helsinki. GCP should be a consistent theme, and clinical trials should adhere to all regulatory requirements. Legal counsel and compliance departments should be involved in certain aspects of the planning and oversight of the clinical trials to ensure regulatory compliance.

Ethical principles that should govern the conduct of clinical trials include:

- Prior to the commencement of a trial, the foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. The safety and welfare of the trial subject must be considered. The anticipated benefits of the trial must justify the risk if the trial is to be initiated and continued.
- Special attention should be paid to naive trial subjects, and there should be a valid scientific rationale for the use of such subjects. The rights, safety, and well-being of the trial subjects should be the most important considerations, and these considerations should prevail over science and society.
- There should be a genuine research question, and the available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.
- Clinical trials should be scientifically sound and described in a clear, detailed, rigorous protocol. The protocol should be consistent with safety and efficiency.
- IRB or Independent Ethics Committee (IEC) approval or a favorable opinion must be obtained prior to initiating the trial, and the trial should be conducted in compliance with the protocol approved by the IRB or IEC. The IRB or IEC should take into consideration the payments that may be made to the trial subjects to ensure that the trial subjects are not unduly influenced to participate in the trial.
- The medical care given to, and medical decisions made on behalf of, the trial subjects always should be under the supervision of a qualified physician or, if appropriate, a qualified dentist. All nonphysician clinical personnel should be adequately supervised.
- Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her assigned task. Adequate training in the protocol-related activities should be provided. The staff on the protocol should be trained appropriately, and that training should be documented. The study staff should be familiar with the clinical trial standards and regulatory requirements.
- Every trial subject should give his or her informed consent freely prior to participation in the clinical trial. That consent, as well as the process and procedure leading up to obtaining the consent, should be documented appropriately. The subjects' education level and language skills should be taken into consideration and documented appropriately, should there be a question later.
- All clinical trial information should be documented appropriately, including recording, handling, and storing such information in a manner that allows its accurate reporting, interpretation, and verification. Particular attention should be paid to the electronic storage and encryption of such information.

- The confidentiality of trial subject records is of paramount importance. Records that could identify the trial subject must be protected. Adherence to privacy and confidentiality rules and regulations for the particular jurisdictions involved also is crucial.
- Investigational products should be manufactured, handled, and stored in accordance with GMP and used in accordance with the approved protocol. All systems with procedures should assure the quality of every aspect of the clinical trial.

New standards for foreign clinical trials[2]

The FDA issued new regulations on April 28, 2008, revising the standards under which the agency will accept data from foreign clinical trials in support of domestic applications and submissions.[3]

Under the revised regulations, foreign clinical trials to be used as support for an IND, new drug approval (NDA), or abbreviated new drug approval (ANDA) application must be conducted pursuant to the oversight of an IEC and in compliance with the FDA's GCP regulations.

The revisions to the regulations for foreign, non-IND clinical trials require sponsors to: (1) demonstrate that the studies are conducted in accordance with GCP; and (2) permit the FDA to validate the data through onsite inspection. Compliance with GCP requires, among other things, patient informed consent, investigator statements, and adverse event and periodic reporting to the FDA.[4]

The GCP regulations also require that the study be conducted under the oversight of an IEC—"a review panel that is responsible for ensuring the protection of the rights, safety, and well-being of human subjects involved in a clinical investigation and is adequately constituted to provide assurance of that protection."[5]

The GCP standards require IEC review and approval of the study protocol before initiation of a study, continuing IEC review of an ongoing study, and IEC approval for obtaining and documenting informed consent.

The revised regulations describe the information that must be provided when a clinical trial sponsor submits foreign clinical data to the FDA in support of an IND, NDA, or ANDA.[6]

These data submission requirements include a description of investigator qualifications, research facilities, drug product, study protocols, and results. To enhance FDA oversight and facilitate FDA review, sponsors also must document compliance with GCP and IEC procedures. Specifically, when submitting foreign clinical data to the FDA, sponsors must identify the IEC, document the IEC decision to approve or modify the study, describe the methods for obtaining informed consent and any incentives provided to subjects, describe study monitoring procedures, and describe the training provided to ensure compliance with GCP and the approved protocol. The FDA also has added a record retention requirement,[7] which lasts for two years after the agency's decision on an application for marketing approval or, if a study is submitted in support of an IND but not an application for marketing approval, for two years after the submission of the IND. The purpose of this record retention requirement is to enable FDA onsite inspection, if necessary.

The new regulation becomes effective October 27, 2008, and will be applicable to all foreign clinical studies regardless of the status of subject enrollment, whether ongoing, completed, or not yet initiated. To decrease the potential for confusion about which version of the regulations governs a particular foreign trial, the new regulations do not grandfather trials in progress. The new requirements for the design, conduct, and reporting of foreign clinical trials will apply equally to studies that result in NDA and ANDA applications for domestic marketing approval.

Conclusion

As clinical trials across the world continue to increase, it will be increasingly important to know how to conduct such trials not only in the U.S., but also in the EU and Eastern Europe. Adherence to principles of GCP guidance will be important, and GCP will evolve over time in the best interests of trial subjects and the integrity of clinical trials.

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Portions of this article were adapted from David Clark, Paul DeMuro, & John Steiner, Fundamentals of Research, Health Care Compliance Association Research Compliance Conference, Oct. 31, 2007, Chicago, Illinois.

1 *Directive 2001/20/EC of the European Parliament and the Council of 4 April 2001 on the approximation of the laws, regulations, and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use*, Official Journal of the European Communities, L121/34, May 5, 2001.

2 This section was adapted from Carolyne Hathaway, John Manthei, & Cassie Scherer, "New FDA Regulation Alters Standards for Foreign Clinical Trials," Latham & Watkins LLP Client Alert, No. 709, May 29, 2008.

3 21 C.F.R. §312.120.

4 21 C.F.R. Part 312, Subpart D.

5 21 C.F.R. §312.3.

6 21 C.F.R. §312.120(b).

7 21 C.F.R. §312.120(d).

Stark

CMS approves software licensing arrangement

A hospital system's proposal to license a custom software interface ("Physician Practice Interface") to the physicians on its medical staffs for the sole purpose of ordering or communicating the results of laboratory tests and procedures would not result in an improper compensation arrangement, according to a recent CMS advisory opinion. The arrangement, therefore, would not run afoul of the prohibition against physician self-referral (Social Security Act §1877(h)(1)(A) ("Stark law")).

Proposed arrangement. The hospital system contracted with a vendor to install a proprietary health care information system, including a software interface engine that facilitates access through the Physician Practice Interface. Currently, the hospital system's medical staffs can view patient laboratory reports over a protected internet connection to the information system.

Under the proposed arrangement, the hospital system would integrate its information system with the physicians' electronic health records (EHR) systems such that the Physician Practice Interface could be used by medical staff physicians to order or communicate the results of laboratory tests and procedures furnished by the hospital system.

Analysis. Under §1877(h)(1) of the Social Security Act, CMS explained, a "compensation arrangement" is defined as "any arrangement involving any remuneration between a physician…and an entity, other than an arrangement involving only…[t]he provision of items, devices, or supplies that are used solely…to order or communicate the results of tests or procedures for such entity."

The hospital system certified that: (1) the interface would be used only to order or communicate the results of tests and procedures furnished by the hospital system; (2) it could not be applied to perform any alternative functions; and (3) the medical staff could not sell, transfer, or otherwise assign the license to use the interface. Accordingly, the proposed arrangement would not constitute a "compensation arrangement" under the Stark law, CMS concluded. ■

CMS Advisory Opinion, No. CMS-AO-2008-01, May 2008, Health Care Compliance Reporter ¶350,084.

In the News

Secretary names EHR demonstration participants

The 12 communities that will participate in a national Medicare demonstration project that provides incentive payments to physicians for using certified electronic health records (EHRs) to improve the quality of patient care were identified by HHS Secretary Michael Leavitt. The communities selected to work with CMS, which range from county- and state-level to multi-state collaborations, are: Alabama, Delaware, Jacksonville, Florida (multi-county), Georgia, Maine, Louisiana, Maryland/Washington, D.C., Oklahoma, Pittsburgh, Pennsylvania (multi-county), South Dakota (multi-state), Virginia, and Madison, Wisconsin (multi-county). The five-year, first-of-its-kind project is expected to improve the quality of care provided to an estimated 3.6 million Americans. Financial incentives will be provided to as many as 1,200 primary care physician practices in the selected communities that use certified EHRs to improve quality as measured by their performance on specific clinical quality measures. In addition, bonus payments may be awarded based on a standardized survey measuring the number of EHR functionalities a physician group has incorporated into its practice. Total payments under the demonstration for all five years may be up to $58,000 per physician or $290,000 per practice. Findings from the demonstration will help: (1) determine the role of EHRs in delivering high-quality care and reducing errors; and (2) assess the role of incentive payments in encouraging adoption and use of EHRs.

CMS Press Release, June 10, 2008.

Lawmakers tout health IT, encourage privacy initiatives

Lawmakers and industry officials marked the 12th annual National Health Information Technology (IT) Week on Capitol Hill with a call to fully integrate technology in the health care market. At a press conference on June 10, 2008, Rep. Allyson Swartz (D-Penn.) said boosting the use of computer technology in the health care market will result in safer and higher quality care and could help lower the number of uninsured Americans. The conversation on ways to boost health IT is just beginning, but one of the prime issues under discussion will be maintaining the privacy rights of patients, said Aneesh Chopra, Virginia Secretary of Technology. Chopra explained that states should partner with the federal government, private industry, and nonprofit organizations to support privacy initiatives that protect patients. He said the health care industry is working to provide the same level of protection for patient data that customers who use online banking expect for their financial data.

CCH Washington Bureau, June 10, 2008.

Senators offer plan to halt physician payment cuts

A plan to stop physician pay cuts from taking effect on July 1, 2008, has been outlined by Senate Finance Committee Republicans. According to a summary released on June 4, 2008, by ranking member Charles Grassley (R-Iowa), the GOP plan would continue a scheduled 0.5 percent increase through December 31, 2008, and provide an additional 1.1 percent update for 2009. The 2009 update was recommended by the Medicare Payment Advisory Commission (MedPac). Democrats, meanwhile, are working on their own plan, which does not include the increase recommended by MedPac. Both plans would stop a more than 10 percent cut to Medicare physician reimbursement rates for 18 months and would provide incentives for electronic prescribing. Although Grassley offered the proposal, he would like to restart negotiations with Democratic leaders on a Medicare bill, according to his office. Talks between both parties stalled in May.

CCH Washington Bureau, June 4, 2008.