WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 28th Year of Publication

Vol. 28, No. 21, September 10, 2007

CMS Wraps Up Stark Rulemaking, But With Twists At The End

Join us on Tuesday, October 2, for our special audio conference on what the new Stark rules mean for labs, pathologists, and radiologists. Registration and other details at *www.g2reports.com*

Concluding some nine years of rulemaking on the Stark physician self-referral law, the Centers for Medicare & Medicaid Services has published the final Phase III regulations implementing the statute and its numerous exceptions. The Phase III regulations were published in the September 5 *Federal Register* and take effect December 4 of this year. The Phase III rule finalizes the Phase II interim final rule published March 26, 2004 and responds to public comments on Phase II.

In the Phase III final, CMS added no new exceptions to the Stark statute, but did seek to clarify certain definitions and exceptions. It included provisions to scale back the exception for indirect compensation arrangements and to eliminate the safe harbor for using hourly payments to doctors for personal services when determining fair market value compensation. On the issue of fair market value, CMS again shied away from a precise definition, saying, "Ultimately, the appropriate method for determining [this] value for purposes of the Stark law depends on the nature of the transaction, its location, and other factors."

CMS advised providers to consult all phases of the Stark rulemaking to get a full understanding of how the statute and its different exceptions apply to referral business arrangements. "Phases I, II, and III are intended to be read together as a unified whole. Phase I contains a legislative and regulatory history of the law, which is not repeated here," the agency said in the Stark III preamble. *Continued on p. 2*

CLIAC Urged to Embrace Legislative Reform for CLIA Cytology Proficiency Testing

A major cytology coalition has called on the Clinical Laboratory Improvement Advisory Committee to adopt a legislative solution to change CLIA gynecologic cytology proficiency testing, saying the current regulatory route is going nowhere.

Speaking before CLIAC on September 5 on behalf of the Cytology Proficiency Improvement Coalition, which includes 60 national and state organizations, George G. Birdsong, MD, FCAP, said that while the panel's efforts to advance regulatory recommendations "have been appreciated, we believe enactment of H.R. 1237, the Cytology Proficiency Improvement Act of 2007, is a better approach." The legislation was introduced in the House earlier this year; there is as yet no Senate counterpart (*NIR, 28, 10/Mar 12 '07, p. 2; 28, 13/Apr 23 '07, p. 4*). *Continued on p. 4*

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Providers should be aware that Medicare/ Medicaid referral arrangements with physicians must be compliant with the final Stark rules by early December. But existing contracts that comply with existing rules are grandfathered until the end of the contract term, according to CMS.

Also, now that it has concluded formal Stark rulemaking, look for CMS to use the Medicare physician fee schedule rule as the vehicle for further Stark changes.

Stark Rulemaking, *from p. 1*

The self-referral ban, called Stark after its chief congressional sponsor, Democratic Rep. Pete Stark (CA), prohibits physicians from referring Medicare or Medicaid patients to facilities with which they have a financial interest, whether by ownership or by compensation arrangements or both, unless the physicians qualify for a number of exceptions to the ban. The original Stark ban (I) prohibited Medicare referrals for clinical lab services; the revised Stark ban (II) added 10 other "designated health services" and prohibited Medicaid referrals as well.

For an analysis of some Stark III changes of import to labs, *NIR* turned to attorney Robert E. Mazer, with Ober/Kaler in Baltimore, MD. In our last issue, he correctly cautioned providers that CMS likely had finalized a "stand in the shoes" provision that could have a big impact on contractual arrangements now considered "indirect compensation" (*NIR, 28, 20/Aug 13 '07, p. 4*).

"Under the new regulations," Mazer said, "when a lab has a contract arrangement with a group practice or other 'physician organization,' each physician who practices as part of that organization is deemed to have a direct financial interest with the lab. Therefore, one of the exceptions applicable to direct compensation requirements must be satisfied.

What's been added to the regulations is a limited "stand in the shoes" provision, he continued. "Under the revised rules, the existence of a physician organization is effectively disregarded. However, other types of entities wouldn't be similarly ignored. For example, if a physician were a shareholder in a management company that furnished services to a lab, the physician would still be deemed to have only an indirect compensation arrangement with the lab. The less onerous exception for such an arrangement would be applicable."

There are several interesting discussions CMS makes, Mazer said, related to services that are performed or supervised by a physician who has an independent contractor relationship with a group practice. Independent contractors are considered a "physician in the group practice," but not a "member" of the group. A "physician in the group practice" may furnish or supervise services under the exception for "physicians' services" and may supervise services under the exception for "in-office ancillary services."

According to CMS, Mazer noted, an independent contractor is considered to be a "physician in the group practice" only when he or she is performing services within the group practice's facilities. Therefore, an independent contractor supervising services under either exception must be on the group practice's facilities when the services being supervised are being performed. "Such a policy would clearly be subject to challenge if applied to clinical lab tests and other diagnostic procedures where on-site supervision is not required by applicable Medicare payment and coverage rules which govern the level of supervision required under the relevant Stark exceptions," he said.

CMS also modified the definition of "physician in the group practice" to require that an independent contractor physician have a direct contract with a group practice. A physician employed by a lab could not, for example, furnish or supervise services under either exception as part of a group practice arrangement if his services were being provided to the group under a contract between the lab and the group practice. "This may reflect CMS' concern regarding the nature of financial

relationships between labs and pathology groups and medical practices that permit medical practices to profit from pathology procedures for their own patients," Mazer observed.

Finally, CMS raised a substantial question as to whether prototypical shared laboratory arrangement—where tests are performed simultaneously for each participant in the arrangement—continue to be permissible, Mazer said. According to CMS, each participant must control the facility and staffing when services are being furnished to its own patient. CMS states that, "as a practical matter, this likely necessitates a block lease arrangement" under which each participant would use the facility during a discrete time period. Such a change in policy would potentially upset hundreds or thousands of long-standing arrangements.

CAP, ACLA Continue Challenge to FDA on Lab-Developed Tests

In late July, the Food & Drug Administration issued some changes to its revised draft guidance requiring, for the first time, premarket review of certain types of lab-developed tests (LDTs), known as in vitro diagnostic multivariate index assays (IVDMIAs). These tests typically combine assays and proprietary algorithms to produce patient-specific results (*NIR, 28, 19/Jul 30 '07, p. 8*).

The deadline for comments on the latest version ended August 27, and the College of American Pathologists and the American Clinical Laboratory Association again registered fundamental concerns with FDA's expanded oversight of these genetic and other testing services and with its definition of IVDMIA, which they contend is still too subjective and open to conflicting and confusing interpretations.

Both groups challenge the FDA's assertion that it has statutory authority to regulate LDTs as class II or III medical devices. ACLA argued: "LDTs are neither medical devices nor commercially distributed among states, both requirements for FDA jurisdiction. The components of LDT processes are not marketed as kits or test systems, and they are not physically distributed or delivered outside the lab. Instead, labs provide written reports of the results to the ordering physicians after the labs have performed the tests. Thus, clinical labs that develop and perform LDTs are merely providing *services* to outside entities as opposed to any identifiable medical devices." CAP and ACLA note that LDTs already are highly regulated under CLIA quality system requirements.

CAP called on the FDA to reassess whether this guidance represents "the best way forward." CAP and ACLA continue to contend that the agency should follow a formal rulemaking procedure, given the significant expansion of authority that the FDA is making. But the FDA still holds that the process for issuing guidance documents on the subject offers sufficient opportunity for public comments. So, if the FDA goes ahead along this route, ACLA said more extensive meetings and dialogue are needed between the agency and the industry and a longer time frame for labs to adapt to any final guidance should be granted.

CMS Rejects Petition for Tougher Genetic Testing Standards

While the FDA forges ahead to expand IVDMIA oversight, the Centers for Medicare & Medicaid Services has rejected a petition from a coalition of health and consumer groups to create a genetic testing specialty under CLIA. CMS said it would instead beef-up CLIA quality system standards for such testing, which already is subject to the most stringent CLIA test performance controls.

The petition was filed jointly in September 2006 by the Genetics & Public Policy Center, Public Citizen, and the Genetic Alliance. In reacting to the decision, Kathy Hudson, director of the Genetics & Public Policy Center, faulted CMS for putting "cost considerations above the public health."

CMS told CLIAC last year that it was pulling the plug on years of effort to write a rule for a genetic testing specialty under CLIA (*NIR, 28, 1/Oct 9 '06, p. 1*).

CLIA cytology PT has been highly controversial since CMS began nationwide enforcement of the rules in January 2005. Critics say the rules, written in 1992, don't reflect changes in cytology science and practice since then.

CLIA Cytology Proficiency Testing, *from p. 1*

Birdsong, who is director of anatomic pathology at Grady Health System in Atlanta, GA, and associate professor of pathology & laboratory medicine at Emory University, School of Medicine, noted that H.R. 1237 would:

- ❑ Suspend the current proficiency testing program effective upon enactment.
- ❑ Substitute a requirement that labs ensure that all individuals involved in screening and interpreting Pap tests participate annually in a continuing medical education (CME) program that tests their locator, recognition, and interpretive skills.
- ❑ Require that the CME program be approved by the Accrediting Council for Continuing Medical Education or the American Academy of Continuing Medical Education.
- ❑ Require the lab to maintain a record of the cytology CME results of each individual. Accrediting organizations will inspect these results during regular lab inspections required by CLIA.

"The repeated delays and the absence of even a draft or proposed regulation, in our view, demonstrate how untimely and ineffective the regulatory process is for updating professional standards," Birdsong said. "For example, by our projection, the process of revising the cytology PT rules that began in 2006 will likely not be completed until 2009, meaning at least five years will have elapsed since the profession began requesting changes to the regulation in 2004." Moreover, CMS has ruled off the table any proposed changes to the CLIA statute.

FDA Okays Roche's WNV NAT to Screen Blood, Organs

The Food & Drug Administration announced August 28 that it has cleared for market Roche's nucleic acid test (NAT) to screen blood and organs for infection with West Nile Virus (WNV). The cobas TaqScreen WNV test—made by Roche Molecular Systems Inc., Pleasanton, CA—is an automated NAT that is able to detect the genetic material of the virus early in the infection, the FDA noted.

The director of FDA's Center for Biologics Evaluation & Research, Jesse L. Goodman, MD, MPH, said, "Blood centers and hospitals now have a choice of two FDA-approved NATs for WVN blood screening." The first automated WNV NAT to get FDA approval was the Procleix WNV Assay on the Procleix TIGRIS system, manufactured by Gen-Probe Inc. (San Diego)

West Nile Virus: Hitting Hard This Year

- ❑ WNV has been especially virulent this year. Although it is still early in the WNV season, 58 blood donors who are possibly positive for the virus have been reported to the CDC as of August 21, 2007.
- ❑ Most often, WNV is transmitted to humans by mosquitoes, but also can be transmitted (in addition to blood transfusion) by organ transplantation from infected donors.
- ❑ While WNV infection is common in Africa, Asia, and the Middle East, it did not appear in the United States until 1999. Since then, it has become endemic in most of the country, with from 1 million to 3 million cases between 1999 and 2006, according to the CDC.
- ❑ Most people infected with WNV show no signs of the disease but about 1 in 150 to 1 in 350 infected people will develop serious symptoms, including encephalitis, an inflammation of the brain.
- ❑ Since the introduction of the virus, the reported number of human cases of serious WNV in the United States has grown steadily from 62 in 1999 to 4,269 in 2006.

Source: Food & Drug Administration.

and marketed by Chiron Corp. (Emeryville, CA), a Novartis business (*NIR, 28, 11/Mar 26 '07, p. 6*).

Roche's cobas TaqScreen WNV test is approved for the detection of the virus in plasma specimens from human donors of whole blood and blood components (plasma, red or white cells, platelets) and living donors of cells, reproductive cells, and other tissues. It is also intended for use in testing plasma specimens of organ donors when specimens are obtained while the donor's heart is still beating. As is true of the Procleix system, Roche's test is not intended for use on samples of cord blood or as an aid in the diagnosis of WNV infection.

The agency's approval comes as it is preparing guidance on possibly requiring blood establishments to use licensed WNV screening tests for blood donors, now that more than one approved test is available. NAT testing improves blood and organ safety, the FDA notes, detecting whether donated blood and organs have been infected even before the donor's body has begun to produce antibodies against the virus.

N·P·I Update

NPPES Provider Data Now Available, CMS Announces

The National Provider Identifier (NPI) Registry became operational on September 4 and a downloadable file will be ready approximately one week later, the Centers for Medicare & Medicare has announced. The data are derived from the National Plan & Provider Enumeration System (NPPES), and CMS had planned to release the data on August 1, but postponed it until September, saying healthcare providers needed more time to verify the accuracy of their NPPES data (*NIR, 28, 20/Aug 13 '07, p. 8*).

Release of the data has been a move long awaited by providers who had argued that a big reason for lack of NPI readiness was lack of access to a centralized database to obtain NPIs and arrange for a smooth exchange of NPIs with trading partners. Otherwise, getting NPIs is time-consuming and costly, with providers having to collect them by going from one trading partner to another.

The NPPES data that CMS has determined to be "disclosable" under the Freedom of Information Act (FOIA) will be available via the Internet in two forms: a query-only database, known as the NPI Registry, and a downloadable file. CMS has posted several documents to help providers understand what the downloadable file will look like, including a "Read Me" file, Header File, and Code Value document for the downloadable file on the CMS NPI Web page at *http://www.cms.hhs.gov/NationalProvIdentStand/06a_DataDissemination.asp*.

The National Provider Identifier is one of a series of identifiers required by HIPAA (the Health Insurance Portability & Accountability Act of 1996) to facilitate electronic healthcare data exchange. It is a unique 10-digit numeric identifier that neither expires nor changes. It replaces all existing legacy provider numbers.

NPI use has been required as of May 23, 2007, but CMS has allowed contingency plans for entities that could not meet the deadline, but are making a good-faith effort to comply as quickly as possible. As of May 23, 2008, Medicare will recognize only NPIs in HIPAA standard electronic transactions.

NPI Update, *continued*

Some key data elements that are FOIA-disclosable are, CMS notes:

- ❑ NPI
- ❑ Entity Type Code (1-Individual or 2-Organization)
- ❑ Replacement NPI
- ❑ Provider Name (First/Middle/Last, Prefix, Suffix, Credential(s), OR the Legal Business Name for Organizations)
- ❑ Provider Other Name (First/Middle/Last OR 'Doing Business As' Name, Former Legal Business Name, Other Name for Organizations)
- ❑ Provider Business Mailing Address (First line address, Second line address, City, State, Postal Code (and Country Code if outside the U.S.), Telephone/Fax Number)
- ❑ Provider Business Location Address (First line address, Second line address, City, State, Postal Code (and Country Code if outside the U.S.), Telephone/Fax Number)
- ❑ Healthcare Provider Taxonomy Code(s)
- ❑ Other Provider Identifier(s)
- ❑ Other Provider Identifier Type Code
- ❑ Provider Enumeration Date
- ❑ Last Update Date
- ❑ NPI Deactivation Reason Code
- ❑ NPI Deactivation Date
- ❑ NPI Reactivation Date
- ❑ Provider Gender Code
- ❑ Provider License Number
- ❑ Provider License Number State Code
- ❑ Authorized Official Contact Information (First, Middle, Last Name, Title or Position, Telephone Number)

Claims Rejection Alert for Providers

Between September 3, 2007 and October 29, 2007, local Medicare contractors will begin to turn on edits to validate the NPI/Legacy pairs submitted on claims. If the pair is not found on the Medicare NPI crosswalk, the claim will be rejected.

Your contractor is to advise you as to the particular time frame for the transition. And the contractor is to inform you a minimum of seven days prior to turning on the edits, so you can validate the NPI/Legacy pairs against the Crosswalk.

If you are receiving informational edits today, CMS strongly advises, validate that the NPPES has ALL of the NPI and legacy numbers you intend to use on claims and for billing purposes. If NPPES is correct, and you continue to receive information edits, ask your contractor to validate the provider information in its system. If the contractor information is not correct, you may be instructed to submit an enrollment form or CMS-855. If the information is different in the two systems, there is a very good chance your claim will reject, CMS warns. NPPES data may be verified at *https://nppes.cms.hhs.gov*.

If the provider does not respond within 14 calendar days to this communication, the contractor will return the claim as "unprocessable." If the provider does respond, it may furnish the legacy number over the phone.

♦ MEDICARE CLAIMS *Advisory*

New 'Date of Service' Policy for Lab Specimens

As of January 1, 2008, Medicare will implement its revised policy on the date of service (DOS) for laboratory specimens. The policy took effect as part of the final 2007 physician fee schedule, but its launch in the claims processing arena was scheduled for a year later.

In alerting local contractors to the change, the Centers for Medicare & Medicaid Services offered a step-by-step guide to the new policy (Change Request 5573, August 17, 2007).

General rule: The DOS of the test must be the date the specimen was collected.

Variation: If a specimen is collected over a period that spans two calendar days, the DOS must be the date the collection ended.

Exceptions:

• ***DOS for tests on stored specimens***

If the specimen was stored for less than or equal to 30 calendar days from the date it was collected, the DOS of the test must be the date the test was performed only if:

- ❑ The test is ordered by the patient's physician at least 14 days following the patient's discharge from the hospital;
- ❑ The specimen was collected while the patient was undergoing a hospital surgical procedure;
- ❑ It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- ❑ The results of the test do not guide treatment provided during the hospital stay; and
- ❑ The test was reasonable and medically necessary for treatment of an illness.

> Note: If the specimen was stored for more than 30 calendar days before testing, the specimen is considered to have been archived, and the DOS of the test performed on it must be the date the specimen was obtained from storage.

• ***DOS for chemotherapy sensitivity tests on live tissue***

The DOS of the test must be the date the test was performed only if:

- ❑ The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;
- ❑ The specimen was collected while the patient was undergoing a hospital surgical procedure;
- ❑ It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- ❑ The results of the test do not guide treatment provided during the hospital stay; and
- ❑ The test was reasonable and medically necessary for treatment of an illness.

> Note: In applying the above exception, CMS defines a "chemotherapy sensitivity test" as "a test that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents."

CMS Rule Aims to Reduce Transfusion Risk for Hepatitis C

About 4,980 Medicare and Medicaid participating hospitals will be affected by the rule. HCV infection is the most common chronic blood-borne infection in the U.S.

CMS has published an interim final rule establishing a series of requirements that are intended to reduce the risk of hepatitis C infection in the transfusion of blood and blood components. The rule, published in the August 24 *Federal Register* with a comment period until October 23, will take effect February 20, 2008.

The interim rule, which adopts many requirements laid out in a November 16, 2000 proposed rule, directs hospitals and other facilities that transfuse blood and blood components to:

- ❑ Establish and maintain a written agreement with a regularly used blood bank governing procurement, transfer, and availability of blood and blood components;
- ❑ Quarantine prior collections from a donor who is at increased risk for transmitting HCV infection;
- ❑ Extend the time for maintaining adequate records of the source and disposition of all units of blood and blood components from five years to at least 10 years from the date of disposition; and
- ❑ Make reasonable attempts to notify a patient or the attending physician that they have received potentially HCV infectious blood or blood components when this occurs, as well as notify them of the need for HCV testing and counseling.

 NATIONAL INTELLIGENCE REPORT (ISSN 0270-6768) is published twice monthly (except August and December, which are one-issue months) by Washington G-2 Reports, 3 Park Avenue, 30th Floor, New York, NY 10016-5902. Telephone: (212) 244-0360. Fax: (212) 564-0465. Web site: www.g2reports.com. Order Line: (212) 629-3679.

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