G2 INTELLIGENCE

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Covering Government Policy For Diagnostic Testing & Related Medical Services

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ICD-10 Compliance Date Moved to October 2014

The proposed rule on ICD-10 compliance is to be published in the April 17 Federal Register *and comments are due by May 17.*

In a proposed rule announced April 9, the Centers for Medicare and Medicaid Services (CMS) said it would delay the compliance deadline for use of the *International Classification of Diseases, 10th Revision* (ICD-10) diagnosis and procedure code sets from Oct. 1, 2013, until Oct. 1, 2014.

The agency had previously announced that it would postpone the October 2013 deadline, citing provider concerns that more time was needed to make the major switch from the current ICD-9 code sets but did not specify a new target date (*NIR 12, 4/Feb. 23, p. 5*).

All transactions subject to rules under the Health Insurance Portability and Accountability Act (HIPAA) will be required to use ICD-10 codes once the new compliance date is finalized.

In the proposed rule, CMS acknowledges that since the initial final ICD-10 rule was issued in 2009 with a compliance date of 2013, "a number of other statutory initiatives were enacted, requiring health care provider compliance and reporting.

"Providers are concerned about their ability to expend limited resources to implement and participate in initiatives that all have similar compliance timeframes," including Medicare and Medicaid incentive

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House Repeals Payment Advisory Board; Senate Not Likely to Go Along

The GOP-controlled House has voted to repeal the controversial Independent Payment Advisory Board (IPAB) created by the health care reform law and designed to help control Medicare costs.

Repeal of the IPAB is contained in legislation (H.R. 5) that puts major limits on medical malpractice lawsuits brought in state court, including a cap of $250,000 for noneconomic damages. It also would preempt existing state laws.

The legislation now goes to the Democratic-controlled Senate where it is expected to be a "nonstarter." The White House also opposes IPAB repeal.

The Obama administration said in a statement, "The bill would repeal and dismantle the IPAB even before it has a chance to work. It would eliminate an important safeguard that, under current law, will help reduce the rate of Medicare cost growth responsibly while protecting Medicare beneficiaries and the traditional program."

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ICD-10 Compliance Date Moved, *from p. 1*

program requirements for meaningful use of electronic health records and the Medicare e-prescribing incentive program.

Industry delays in a successful transition to Version 5010, a prerequisite for accommodating ICD-10, also factored into CMS's decision. "We are concerned that the delays encountered in Version 5010 have affected ICD-10 planning and transition timelines," the proposed rule said.

Compliance with Version 5010 had been required Jan. 1 of this year, but CMS twice extended the deadline, most recently on March 15, when it said no enforcement action would be taken against noncompliant entities through June 30 (*NIR 12, 6/March 22, p. 3*).

The proposed rule also would require health plans to adopt a unique identifier for all HIPAA transactions, noting that this "will allow for a higher level of automation for health care provider offices, particularly for processing of billing and insurance related tasks, eligibility responses from the health plans, and remittance advice that describes health care claim payments."

CMS expects to publish a final rule on the unique health plan identifier on Oct. 1 of this year, with a compliance date for all covered entities of Oct. 1, 2014 (small health plans would have an extra year to comply). G2

New Self-Referral Study Backs Closing In-Office 'Loophole'

A new study aims to persuade policymakers to remove pathology from the in-office ancillary services (IOAS) exception under the Stark physician self-referral law.

Since the Centers for Medicare and Medicaid Services thus far has declined to do so, advocates have turned to Congress to close what they term a loophole in the law that allows medical specialty groups to insource pathology work and increase their Medicare revenue stream.

The study's main conclusion: The practice of ordering tests from pathology labs in which treating physicians have a financial stake results in increased utilization, higher Medicare spending, and lower rates of cancer detection.

The study, conducted by researchers at Georgetown University in Washington, D.C., and published in the April issue of *Health Affairs*, was funded by the College of American Pathologists (CAP) and the American Clinical Laboratory Association (ACLA).

Researchers, led by health economist Jean Mitchell, Ph.D., compared Medicare billings and prostate cancer detection rates over a three-year period by self-referring practices with other urology groups. They found that:

- On average, self-referring urologists billed Medicare for 72 percent more anatomic pathology specimens than physicians who did not benefit financially from ordering more tests, and
- The prostate cancer detection rate per biopsy episode was significantly higher for men who had the biopsy performed by non-self-referring urologists.

"The implications are clear," said CAP President Stanley Robboy, M.D., FCAP. "Self-referral has created an incentive to spend millions and millions of dollars without any data showing that this practice benefits patients."

ACLA President Alan Mertz noted, "This study suggests that men are at heightened risk of unnecessary and costly prostate cancer biopsies when under the care of a physician who benefits financially through self-referral. This is a serious unintended consequence of a legal loophole that needs to be corrected immediately by Congress."

The Stark Physician Self-Referral Law

- Prohibits a physician (or an immediate family member) from making Medicare and Medicaid referrals for designated health services (which include outpatient hospital services) to an entity with which the physician (or immediate family member) has a financial arrangement, either by ownership interest or compensation arrangements or both.
- Bars billing anyone pursuant to a prohibited self-referral.

In addition to the in-office ancillary services exception, there are numerous others in the statute and related regulations issued by the Centers for Medicare and Medicaid Services.

The Alliance for Integrity in Medicare (AIM) hailed the study as "providing independent, peer-reviewed evidence that this self-referral practice provides no benefit to patients and is only serving to drive up Medicare costs."

The AIM coalition includes, in addition to ACLA and CAP, the American College of Radiology, the American Physical Therapy Association, the American Society for Clinical Pathology, the American Society for Therapeutic Radiation and Oncology, the Association for Quality Imaging, and the Radiology Business Management Association.

AIM has lobbied Congress to remove anatomic pathology, advanced diagnostic imaging, physical therapy, and radiation therapy from the IOAS exception (*NIR 11, 18/Oct. 6, p. 3*). The alliance says the new study "underscores for policymakers that self-referral is a serious problem that needs to be addressed."

Arguments Pro and Con

Medical specialty practices have defended their use of the in-office ancillary services exception, saying it enables them to make rapid diagnoses and initiate treatment during a patient's office visit, improves care coordination, and encourages patients to comply with diagnostic and treatment recommendations.

AIM argues that these arrangements flout the rationale for establishing the in-office exception, namely, "to allow physicians to offer services integral to a single visit to the physician office."

A common feature of anatomic pathology, advanced diagnostic imaging, physical therapy, and radiation therapy is "that each requires time to complete outside of an office visit, specialized training, and independent professional judgment to perform."

The full Georgetown University study is available at the ACLA Web site at *www.acla.com* and *www.healthaffairs.org*.

Myriad Gene Patent Case Remanded for Further Review

The U.S. Supreme Court has vacated a lower court ruling upholding Myriad Genetics' patents on the BRCA1 and BRCA2 genes associated with hereditary breast and ovarian cancer and remanded the case to the U.S. Court of Appeals for the Federal Circuit for consideration in light of the high court's recent decision invalidating two test process patents held by Prometheus Laboratories.

The case, *Mayo v. Prometheus*, involved patents for a blood test used to determine the proper dosage of thiopurine for patients with gastrointestinal and nongastrointestinal autoimmune diseases like Crohn's disease, based on the rate at which each patient metabolizes the drug. Prometheus, a unit of Switzerland-based Nestle S.A., was the exclusive licensee of the patents.

In a unanimous decision the high court March 20 ruled that the Prometheus patents were not patent-eligible because they merely describe the laws of nature and "add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity" (*NIR 12, 6/March 22, p. 1*).

Now, the same three-judge panel that ruled in favor of Myriad Genetics must review its decision. It can ask for a further briefing and even oral arguments about how the *Prometheus* case affects its decision, and the judges could arrive at the same decision or a different one, said Sandra Park, an attorney with the American Civil Liberties Union (ACLU), which represents plaintiffs in the suit, including the College of American Pathologists (CAP). In CAP's April 12 *Statline*, she noted, "Depending on the new judgment, we or Myriad would once again have an opportunity to petition for Supreme Court review."

Core of the Controversy

In a 2-1 decision released July 29, 2011, the appellate court overturned a lower court's ruling that the Myriad gene patents were invalid because the genes are products of nature (*NIR 11, 15/August, pp. 1, 4-5*). Instead, the appellate court found that the Myriad patents are valid because they involve DNA isolates "markedly different" in molecular composition from the DNA that exists in chromosomes in the body.

In light of conflicting court decisions, the big question for health care providers and biotechnology and pharmaceutical industries remains: What, if any, human genes and their applications are patent-eligible? Nearly 20 percent of human genes already are patented, including genes associated with Alzheimer's disease, muscular dystrophy, colon cancer, asthma, and many other illnesses.

Then in mid-September 2011 the court turned down petitions by both sides to again air arguments in the case, prompting both sides to petition for Supreme Court review (*NIR 11, 18/Oct. 6., p. 5*).

The ruling favoring Myriad has been hailed by the biotechnology and diagnostics industries. But a broad coalition of providers, researchers, and patients that filed suit against Myriad say the breast and cancer gene patents give the company a monopoly on the testing, stifling research and curtailing women's access to a lifesaving test. As the patent holder, Myriad has the exclusive right to perform testing on the BRCA genes, license the testing to other users, and threaten litigation against any unlicensed use.

Pathology Alert: CMS Delays POS Code Changes

The Centers for Medicare and Medicaid Services (CMS) is delaying until Oct. 1 its revised instructions on assigning place-of-service (POS) codes for all services paid under the Medicare physician fee schedule and for certain services furnished by independent labs.

The agency had planned to implement the changes April 1 (Transmittal 2407). But in announcing the delay in Transmittal 2435 (March 29), the agency said this would give it time to address questions raised about the national POS policy change, including how it would affect pathology service claims.

This is welcome news to the College of American Pathologists (CAP) and the American Society for Clinical Pathology (ASCP), which sought a delay, noting that the change would significantly alter how pathologists code for POS and that more time and clarifications are needed to minimize the impact on their operations.

CAP and ASCP further noted that if implemented April 1, the change would have caused major confusion in how Medicare contractors process claims submitted by independent labs under the "grandfather" protection. With the change now postponed until Oct. 1, independent laboratories can continue to bill and be paid without interruption for the technical component (TC) of pathology services furnished to "grandfathered" hospitals until July 1, when the TC provision is set to expire.

In the revised instructions, CMS is proposing that:

- The POS code shall be for that setting in which the beneficiary is receiving inpatient care (POS code 21) or outpatient care (POS code 22) from a hospital.
- Pathologists who work from their office or laboratory and receive specimens from hospitals must use POS 21 or 22; claims using POS 11 (physician's office) or 81 (independent lab) will be denied.

The purpose is to ensure that claims paid by Medicare contractors are always paid at the correct facility or nonfacility rates, CMS said. This responds to concerns raised by the Office of Inspector General about the volume of claims for services reported as occurring in the office POS when the services were actually provided in an outpatient hospital or ambulatory service center which are paid at the nonfacility rate, rather than the lower facility rate.

In addition to calling for the POS implementation delay, CAP and ASCP recommended that CMS include in final instructions various clarifications specific to pathology services, including pathology examples, and that pathologists be allowed to use the POS 11 code for procedures performed on archived specimens or on a confirmatory or secondary opinion consultation.

Colorado Enacts Direct Billing Law for Anatomic Pathology

Colorado is the 19th state to enact a direct billing law for anatomic pathology (AP) services. The legislation—HB 1221, which passed both chambers of the state legislature unanimously—was signed into law March 22 by Democratic Gov. John Hickenlooper and takes effect Jan. 1, 2013.

The law mandates that patients may be billed for AP services only by the patholo-

States With AP Direct Billing Laws

Arizona	Montana
California	Nevada
Colorado	New Jersey
Connecticut	New York
Indiana	Ohio
Iowa	Rhode Island
Kansas	South Carolina
Louisiana	Tennessee
Maryland	Washington
Massachusetts	

gist who performs or supervises the testing. This prevents the ordering physician from adding a markup charge to a patient's laboratory bill. Further, any person receiving a bill in violation of the law may take action to recover the actual amount paid.

The College of American Pathologists (CAP) worked with the state's Society of Clinical Pathologists to secure approval of the legislation. CAP and state societies have long opposed the practice of client billing, in which a treating physician realizes a profit by charging a patient full price for a laboratory service the physician received at a discount.

Currently, more than two-thirds of the U.S. population is direct billed for anatomic pathology services under federal and state law, according to CAP.

House Repeals Payment Advisory Board, *from p. 1*

Function of the Board

Beginning in 2014, in any year in which the Medicare per capita growth rate exceeds a target growth rate, the 15-member board, appointed by the president and subject to Senate confirmation, must recommend program spending reductions that would become law unless Congress passes an alternative.

But the law also sets boundaries for the board. It cannot make recommendations that would ration care, increase Medicare beneficiary cost sharing, or otherwise restrict benefits or modify eligibility criteria.

Controversy Over the Board

The IPAB has been a favorite target of Republicans opposed to the health care reform law, but it has also triggered strong objections from business groups and a host of health care providers, including pathology and clinical laboratory organizations.

Its power over Medicare payment policy would be difficult for legislators to override. Under the law, Congress cannot consider any amendment to the IPAB cost-cutting proposal that does not meet the same cost-reduction goals unless both houses of Congress and three-fifths of the Senate vote to waive this requirement. Critics also note the board lacks accountability since it is not required to get public comment on its proposals and its actions are not subject to judicial review.

Provider and business groups also note that much of Medicare spending is exempt from the board's oversight until 2020 (hospital spending, for example), so those most affected by any cuts that must be made are physicians, clinical labs, drug companies, medical device makers, Medicare Advantage plans, Part D prescription drug plans, and beneficiaries.

Supporters of the IPAB say it is intended as a "backstop" to other Medicare reforms by controlling Medicare spending when Congress fails to do so and by law it must focus on provider reimbursement, not beneficiaries.

In a March 7 estimate, the Congressional Budget Office (CBO) said that the spending growth target was unlikely to be hit through 2022, and thus the board would not make recommendations until at least that time. But CBO said that repealing the IPAB would cost $3.1 billion over 10 years.

Getting Paid for Pathology TC in Post-Grandfather Era

The grandfather protection, which allows independent clinical laboratories to bill Medicare directly for the technical component (TC) of pathology services to hospital inpatients and outpatients, is set to expire at the end of June (*NIR 12, 5/March 9, p. 1*). Thereafter, how will these labs get paid for the TC? This question was addressed by Peter Kazon, senior counsel with Alston & Bird (Washington, D.C.), during the March 27 webinar sponsored by G2 Intelligence and the American Clinical Laboratory Association.

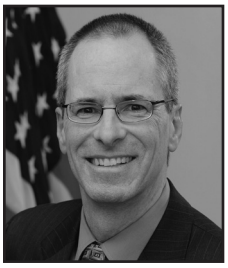
For dates of service on and after July 1, 2012, these labs must bill the hospital for the TC. The hospital will then be reimbursed by Medicare under either the diagnosis-related group (DRG) system or the outpatient prospective payment system (OPPS). For inpatient services, the hospital will get no additional payment because the TC is considered part of the DRG payment. Under OPPS, the hospital will bill for the TC and be paid based on the following ambulatory payment classifications (APCs, adjusted for the hospital wage index and subject to a 20 percent copayment):

APC	DESCRIPTION	BASE PAY	COMMON CODES
0342	Level I, Pathology	$11.16	"-99" codes
0343	Level III, Pathology	$36.81	CPT 88304, 88305
0344	Level IV, Pathology	$57.66	CPT 88307
0433	Level II, Pathology	$17.08	Flow cytometry, TC; special stains
For information on specific codes, see Addendum B at *https://www.cms.gov/HospitalOutpatientPPS/AU/list.asp#TopOfPage*			

How does this interact with the 14-day rule? This rule requires that for biopsy specimens collected in the hospital, the date of service (DOS) depends on when the test is ordered. If ordered 14 days or more after the patient is discharged, the DOS is the date the test is performed. Since the patient is not a hospital patient on that DOS, hospital bundling rules do not apply and the service can be billed to Medicare. If the test is ordered 13 days or less after the patient is discharged, the DOS is the date the specimen is collected. Since the patient is a hospital patient on that DOS, hospital bundling rules do apply and the service must be billed to the hospital.

Does the lab have to bill the hospital for the TC? Yes, Kazon said. If it fails to do so, the hospital is getting something of value at no charge, and this would likely be considered "remuneration" under the anti-kickback law, that is, giving a service to a referrer for no cost or below market value. It could also create a compensation arrangement under the Stark physician self-referral law.

New Chief Counsel Named at HHS Inspector General's Office



Gregory E. Demske

Daniel Levinson, inspector general for the U.S. Department of Health and Human Services (HHS), announced that effective April 1, Gregory E. Demske is appointed his chief counsel, following the retirement of Lewis Morris on April 1.

Demske began his tenure with HHS in September 1990 and has served as assistant inspector general for legal affairs since 2005. He will oversee a staff of 75 professionals who provide a full range of legal services to the inspector general's office, including guidance on personnel matters, advice on audits and evaluations, assistance in the investigation and resolution of health care fraud cases, and compliance guidance and advisory opinions.

National Medical Laboratory Professionals Week
April 22-28, 2012

G2 Intelligence salutes this 37th annual event aimed at raising public and industry awareness of the key role that these professionals play in disease diagnosis and prevention and ensuring quality care and patient safety. Today, more than 300,000 of these professionals around the country perform and interpret more than 10 billion lab tests in the United States every year. Among the week's activities are local events such as displays, open houses, radio and TV spots, and other educational campaigns.

Sponsors: American Society for Clinical Laboratory Science • American Society for Clinical Pathology • American Association for Clinical Chemistry • American Association of Blood Banks • American Medical Technologists • American Society of Cytopathology • American Society for Cytotechnology • American Society for Histocompatibility and Immunogenetics • American Society for Microbiology • Association of Public Health Laboratories • Clinical Laboratory Management Association • College of American Pathologists • National Society for Histotechnology. Promotional materials are available at *www.ascp.org* and at *www.ascls.org*. Also, check other sponsors' Web pages.

Upcoming G2 Events

Webinar (2 p.m. – 3:30 p.m. Eastern)

April 26

Is Automation a Sure Path to Lab Growth? Assessing Needs, Developing Plans, and Implementing the Right Systems

Featured speaker: Robert Boorstein, M.D., Ph.D., Medical Director, Enzo Clinical Laboratories

Conferences

April 17-19

MDx *Next*
Molecular Diagnostics Spring 2012
Gaining the MDxEdge
Fairmont Copley Plaza
Boston
www.mdxconference.com/Home

June 6-8

Lab Outreach 2012
Paris Las Vegas
Las Vegas
www.G2Outreach.com

Oct. 10-12

30th Anniversary Lab Institute
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Jim Curren, Editor; Dennis Weissman, Executive Editor; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, COO and Publisher.

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