G2 INTELLIGENCE

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 34th Year of Publication

Vol. 13, Iss. 5, March 14, 2013

CMS Issues Some Details on Medicare Sequestration Cuts

Questions about reimbursement should be directed, CMS said, to your Medicare claims contractor. The agency has notified contractors that they should be ready to make the required cuts by the April start date.

Under current sequester law, reimbursements to health care providers in Medicare Parts A and B, including clinical laboratories and pathologists, are scheduled to be cut up to a maximum of 2 percent as of April 1. The Centers for Medicare and Medicaid Services (CMS) this month released some details on how the cut will be handled.

In a March 8 provider alert the agency said that in general, Medicare fee-for-service claims with dates of service or discharge on or after April 1 will incur a 2 percent reduction. Claims for durable medical equipment (DME), prosthetics, orthotics, and supplies, including claims under the DME Competitive Bidding Program, will be reduced by 2 percent based on whether the date of service, or the start date for rental equipment or multiday supplies, is on or after April 1.

The payment reduction is to be applied to all claims after determining any applicable coinsurance, deductible, and Medicare Secondary Payment adjustments. Though beneficiary payments for deductibles and coinsurance are not subject to the 2 percent reduction, Medicare's payment to beneficiaries for unassigned claims is.

Financial incentive payments for meaningful use of electronic health records also will be cut by 2 percent, CMS has confirmed, even for those who attested in the program before April 1.

CMS to Deny Claims That Fail Ordering, Referring Provider Edits

Clinical laboratories, pathologists, and a host of other Medicare providers will be affected when as of May 1 the Centers for Medicare and Medicaid Services (CMS) fully implements its edits of claims for ordering and referring providers.

Medicare will deny claims that require an ordering or referring provider to be identified and the provider is not identified, is not currently enrolled in Medicare or has a valid opt-out record (the National Provider Identifier and the provider's legal name must match), and is not of a specialty type that may order or refer the service or item being billed.

The Phase 2 denial edits apply to Part B providers, durable medical equipment suppliers, and Part A home health agencies eligible to bill for services to program beneficiaries. They are intended to weed out fraudulent entities from legitimate health care providers and suppliers, CMS said.

Continued on p. 2

INSIDE *NIR*

www.G2Intelligence.com

© 2013 Kennedy Information, LLC, A Bloomberg BNA Business, 800-531-1026. All Rights Reserved. Reproduction Prohibited by Law.

CMS to Deny Claims, *from p. 1*

During Phase 1, which began in 2009 and ends May 1, contractors continued to process claims for payment but with a warning on the remittance advice that claims may not be paid in the future if the ordering or referring provider is not enrolled in Medicare or is not of a specialty eligible to order or refer.

In Phase 2, claims will not be paid if the ordering or referring provider is not on the national Provider Enrollment, Chain, and Ownership System (PECOS) file and not on the contractor's master provider file, or if the ordering or referring provider is on the contractor's master provider file but is not of a specialty eligible to order or refer.

Under the "match or scratch" edits, clinical labs and pathologists are at financial risk if they bill for tests ordered or referred by providers not in the national PECOS file.

The health care reform law, enacted in 2010, specifies that the PECOS requirement applies to claims for durable medical equipment, prosthetics, orthotics, and supplies and for home health. In an interim rule, CMS added claims for laboratory testing, specialist services, and imaging to the list, using its discretionary authority under the law.

Provider Action Needed

If you order or refer items or services for Medicare beneficiaries and do not have a Medicare enrollment record, you need to submit an enrollment application to Medicare using the Internet-based PECOS or by completing the paper enrollment application (CMS-8550). All enrollment applications, including those submitted over the Internet, require verification of the information reported. Sometimes, Medicare enrollment contractors may request additional information to process the application.

Eligible Ordering, Referring Providers

- Doctor of medicine or osteopathy
- Dental medicine
- Dental surgery
- Podiatric medicine
- Optometry
- Physician assistant
- Certified clinical nurse specialist
- Nurse practitioner
- Clinical psychologist
- Certified nurse midwife
- Clinical social worker

Labs and others that bill for orders or referrals from providers can check the provider's Medicare enrollment status and specialty against the "Ordering Referring Report" at *http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html*; click on "Ordering & Referring Information."

When billing for items or services from ordering and referring providers, be aware that claims denied because they failed the edits do not expose the Medicare beneficiary to any financial liability.

If you believe a claim was denied inappropriately because it did not initially pass the edits, you may file an appeal through the standard claims appeals process.

AARP, ACLA Link Up to Combat Lab Copay Revival

The AARP, a leading advocate for seniors, has joined with the American Clinical Laboratory Association (ACLA) in lobbying key Senate health leaders against the imposition of a copay for Medicare Part B laboratory services. Cost sharing for these services has been waived since the lab fee schedule was enacted in 1984 and took effect in 1985.

In a March 1 joint letter to Senate Finance Committee Chairman Max Baucus (D-Mont.) and the ranking Republican, Orrin Hatch (Utah), the groups spelled out their arguments against what they called "this widely discussed reform concept."

 © 2013 Kennedy Information, LLC, A Bloomberg BNA Business, 800-531-1026. All Rights Reserved. Reproduction Prohibited by Law.

Hatch has recommended that Medicare beneficiary cost sharing be combined into a single annual deductible for both Part A and Part B, that a uniform coinsurance rate be established for amounts above the deductible, and that an annual catastrophic cap be implemented to financially protect seniors in cases of serious health events.

Onerous for Both Beneficiaries and Labs

AARP and ACLA counter that requiring coinsurance of any form for Medicare clinical lab services will only shift costs from Medicare and/or Medigap to beneficiaries. "While in some instances having beneficiaries pay a portion of their health care services may be prudent, in the case of clinical lab services it would be both onerous and impractical. Patients do not determine which lab tests are medically necessary for them to receive; instead, those decisions are made by their personal clinicians according to individual needs. Note that 70 percent of medical decisionmaking is based on clinical laboratory testing.

"Clinical laboratory testing is a referral-based service, and only once the tests are ordered for patients by health care professionals does the clinical laboratory receive the requisition and perform the tests. Since the patient is not directly ordering the tests, adding coinsurance is unlikely to change beneficiary utilization behavior, and therefore will not result in health care cost savings."

Moreover, AARP and ACLA point out, "costs incurred by individual labs, as well as the Medicare program, would increase due to the additional administrative and collection burdens. Collecting coinsurance is uniquely difficult and inefficient for clinical labs because there often is no face-to-face encounter between lab and patient, which causes significant obstacles in obtaining accurate patient information and having realistic opportunities for collection."

AMA, McKesson Team Up on MDx Codes

McKesson's Z-Code™ Identifiers came into the clinical lab and pathology spotlight when Palmetto GBA, the Medicare contractor for California, Nevada, Hawaii, and U.S. Pacific territories, last year began requiring their use in its controversial MolDx program, under which Palmetto determines coverage and payment for molecular pathology tests. That program is run under a separate contract with the Centers for Medicare and Medicaid Services and could go national if the agency opts for this course.

Now the Z-Codes are in the news again as the American Medical Association (AMA) and McKesson have entered into a licensing relationship in which these codes will be grouped and indexed with corresponding molecular pathology codes in the AMA's Current Procedural Terminology (CPT) code set.

AMA introduced its CPT molecular pathology codes in 2012, and Medicare this year recognized them, assigning them to the Part B clinical lab fee schedule with payment rates to be determined by local contractors for their jurisdictions (*NIR 12, 20/Nov. 8, p. 1; NIR 13, 3/Feb. 7, p. 1*).

Mapping Z-Codes to CPT Codes

The licensing relationship, announced Feb. 26, offers health care systems a consistent, transparent way to identify and track MDx tests with identifiers and codes working in tandem, said AMA and McKesson in a joint statement.

The result will be a new reference product that maps Z-Codes to CPT codes. The AMA will use the information that labs and manufacturers submit and then share

Continued on p. 7

 © 2013 Kennedy Information, LLC, A Bloomberg BNA Business, 800-531-1026. All Rights Reserved. Reproduction Prohibited by Law.

focus on: *Health Insurance Reform*

New Rules on Essential Benefits, Consumer Protections

The U.S. Department of Health and Human Services (HHS) has finalized major new rules for individual and small-group plans governing the services they must cover and the protections that must be provided to consumers, as well as risk adjustments to stabilize premiums, beginning in 2014.

The rules institute changes required by the health care reform law (the Affordable Care Act or ACA) and apply to nongrandfathered plans, that is, those that were not in effect March 23, 2010, when the ACA took effect.

The provisions affect health plans whether sold in the individual and small-group markets, both inside and outside of ACA-established state health insurance exchanges. The latter are due to open for enrollment Oct. 1 for plans that take effect in 2014.

Essential Health Benefits

Clinical laboratory services and physician services in hospitals and ambulatory care settings are among the 10 categories of care in the essential health benefits (EHB) package that individual and small-group plans must cover to customers, according to a final rule published in the Feb. 25 *Federal Register* and effective April 26 (*see box*).

While the rule does not specify the scope of the "laboratory services" category (that will be based on a state's EHB benchmark plan), HHS has stipulated that genetic counseling and routine breast cancer susceptibility gene (BRCA) testing must be covered as a preventive service with no cost sharing by the patient when determined appropriate by a woman's health care provider. This is in line with a recommendation from the U.S. Preventive Services Task Force that "women whose family history is associated with an increased risk for deleterious mutations in the BRCA1 or BRCA2 genes be referred for genetic counseling and evaluation for BRCA testing."

Essential Health Benefits

1. Ambulatory patient services
2. Emergency services
3. Hospitalization
4. Maternity and newborn care
5. Mental health and substance use disorder services, including behavioral health treatment
6. Prescription drugs
7. Rehabilitative and habilitative services and devices
8. Laboratory services
9. Preventive and wellness services and chronic disease management
10. Pediatric services, including oral and vision care

Benchmark Plans

States may designate health plans operating in their state to be benchmarks for the EHB package, which is to match typical employer plans. States had until late last December to name a benchmark plan. For those that did not, HHS selected as a default plan the largest small-group plan operating in that state. A list of the benchmark plans appears in Appendix 1 of the final rule.

Levels of Coverage and Actuarial Value

Actuarial value, or AV, is calculated as the percentage of total average costs for covered benefits that a plan will cover. For example, if a plan has an AV of 70 percent, on average, a consumer would be responsible for 30 percent of the costs of all covered benefits.

 © 2013 Kennedy Information, LLC, A Bloomberg BNA Business, 800-531-1026. All Rights Reserved. Reproduction Prohibited by Law.

Beginning in 2014, nongrandfathered health plans in the individual and small-group markets must meet certain AVs or "metal levels": 60 percent for a bronze plan, 70 percent for a silver plan, 80 percent for a gold plan, and 90 percent for a platinum plan. In addition, health insurers may offer catastrophic-only coverage with a lower AV for eligible individuals. Metal levels will allow consumers to compare plans with similar levels of coverage, HHS said. "This, along with consideration of premiums, provider participation, and other factors, will help them make an informed choice."

To standardize the AV calculation by health insurers, HHS is providing a publicly available AV calculator based on a national, standard population, as required by law. Beginning in 2015, HHS will accept state-specific data for the standard population if states choose to submit alternate data for the calculator. Consumer-driven health plans, such as high-deductible plans and health savings accounts, are compatible with the AV calculator, HHS noted.

Genetic counseling and BRCA testing for breast or ovarian cancer must be covered as an essential health benefit with no cost sharing by the patient.

Recognizing that health insurers need some flexibility in meeting the metal levels, HHS has ruled that a plan can meet a particular level if its AV is within two percentage points of the standard. For example, a silver plan may have an AV between 68 percent and 72 percent. In addition, insurers in the small-group market may exceed annual deductible limits to achieve a particular metal level.

No Discrimination on Health Status

Individual and small-group plans are prohibited from denying coverage based on health status. "An insurance issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions." However, this should not be construed, HHS said, to prevent plans from using reasonable medical management techniques.

Consumer Protections

In this final rule, published in the Feb. 27 *Federal Register* and effective April 29, HHS specified key consumer protections guaranteed in Title I of the ACA:

Guaranteed availability and renewability. Nearly all health insurance companies offering coverage to individuals and employers will be required to sell health insurance policies to all consumers. No one can be denied health insurance because they have or had an illness. Also, these companies can no longer refuse to renew coverage because an individual or an employee has become sick. Renewal is at the option of the individual or employee.

Fair health insurance premiums. Health insurance companies offering coverage to individuals and small employers will only be allowed to vary premiums based on age, tobacco use, family size, and geography. Basing premiums on other factors will be illegal. The factors no longer permitted in 2014 include health status, past insurance claims, gender, occupation, how long an individual has held a policy, or size of the small employer.

Single risk pool. Health insurance companies will no longer be able to charge higher premiums to higher-cost enrollees by moving them into separate risk pools. Insurers

 © 2013 Kennedy Information, LLC, A Bloomberg BNA Business, 800-531-1026. All Rights Reserved. Reproduction Prohibited by Law.

must maintain a single statewide risk pool for the individual market and a single statewide risk pool for the small-group market.

Catastrophic plans. Young adults and people for whom coverage would otherwise be unaffordable will have access to a catastrophic plan in the individual market. These plans generally will have lower premiums, protect against high out-of-pocket costs, and cover recommended preventive services without cost sharing.

In preparation for the market changes in 2014 and to streamline data collection for insurers and states, the final rule amends certain provisions of the rate review program. It increases transparency by directing insurance companies in every state to report on all rate increase requests. A new report, HHS said, has found that the law's transparency provisions have already resulted in a decline in double-digit premium increases filed from 75 percent in 2010 to, according to preliminary data, 14 percent in 2013.

Premium Stability

This final rule, published in the March 11 *Federal Register* and effective April 30, is intended to stabilize premiums as new consumer protections begin in the individual and small-group market in 2014. The ACA created three programs for this purpose:

Permanent risk adjustment. This program aims to reduce the incentives for health insurers to enroll only healthier consumers and avoid those with pre-existing conditions. An estimated 27 million uninsured are expected to gain coverage under the law, but it is not yet known how many new enrollees may have costly health problems that could result in "adverse selection" that would push up premiums, HHS noted. To offset this, the program provides payments to insurers that have less healthy enrollees than insurers with healthier enrollees. States that are running an exchange and their own risk adjustment program can propose their own methodology for risk adjustment. HHS is finalizing the methodology it will use when a state chooses not to run its own exchange.

As of March 7, 24 states have conditional approval from HHS to run their own insurance exchanges for individuals and small businesses or to partner with HHS to handle some functions. Seventeen states and the District of Columbia have conditional approval to operate state-based exchanges in line with HHS rules. The seven that will run a partnership exchange with HHS include Iowa, Michigan, New Hampshire, West Virginia, Arkansas, Delaware, and Illinois.

Transitional reinsurance. This three-year program is designed to reduce premiums and ensure market stability by helping issuers cover the costs of high-risk enrollees in the individual market. It will lower premiums in this market by an estimated 10 percent to 15 percent in 2014. The statute sets a fixed contribution amount for the reinsurance program.

Temporary risk corridors. This program protects against uncertainty in rate setting for qualified health plans by limiting the extent of issuer losses and gains. The rule finalizes technical details on how issuers will account for profits and taxes in their risk corridors calculations, which align this program with the medical loss ratio program that requires insurers to devote 80 percent of their costs to medical services (any amount above this level must be sent as a rebate to customers). The rule also delineates mechanisms for issuing tax credits and a 3.5 percent user fee for plans sold in a federally facilitated exchange.

 © 2013 Kennedy Information, LLC, A Bloomberg BNA Business, 800-531-1026. All Rights Reserved. Reproduction Prohibited by Law.

AMA, McKesson Team Up, *from p. 3*

in the McKesson Diagnostics Exchange to assign CPT code mappings where appropriate. Not all Z-Codes will immediately map to a CPT code, and, in many cases, multiple Z-Codes will map to a single CPT code. The new product will be available for licensing from the AMA early in 2014.

"Today, over 3,000 molecular and genetic diagnostics are marketed for clinical use. According to Frost & Sullivan, MDx is the fastest growing sector of clinical pathology lab testing, with revenues expected to reach $6.2 billion by 2014 and a projected compound annual growth rate of more than 11 percent. But the tests' impact has not been clearly articulated and quantified, a challenge that grows exponentially with the introduction of next-generation and whole genome sequencing."
—AMA, McKesson

Connecting Z-Codes with CPT codes is expected to yield many benefits, AMA and McKesson noted. Labs can map their tests to CPT codes where appropriate, identify more precisely which test was performed, and report this with the appropriate CPT code, potentially improving efficiencies in the reimbursement process. Payers will have more detailed information to identify tests performed, track outcomes of specific tests, and analyze their value.

CLIA Update: Whatever Happened to . . .

The proposed rule giving patients (and their authorized representatives) direct access to their own laboratory test results?

It was issued in the Sept. 14, 2011, *Federal Register* to modify regulations under two statutes that restrict such access: the Clinical Laboratory Improvement Amendments (CLIA) and the Health Insurance Portability and Accountability Act (HIPAA). The aim is to further individualize medicine and empower patients to participate in medical care decisions (*NIR 11, 17/Sept. 22, p. 1*).

Currently, the rulemaking is in the clearance process within the Centers for Medicare and Medicaid Services (CMS), with a tentative release date of late summer, an agency spokesperson told *NIR*.

At present, CLIA allows disclosure of lab test results only to "authorized persons" unless state law decrees otherwise. A lab may release test results directly to the patient only if (1) the ordering provider expressly authorizes the lab to do so at the time the test is ordered or (2) state law expressly allows for it.

The proposed rule would override release restrictions in 39 states and territories, encompassing some 22,671 labs that provide approximately 6.1 billion tests annually, CMS noted. It also would modify the HIPAA privacy rule to provide individuals the right to receive their test results directly from the lab by removing the exceptions for labs subject to CLIA.

Labs would have flexibility in how they choose to handle patients' requests for their test report, but patients would have the right to request results in electronic or paper form. In instances where anonymous testing is performed, the lab is not required to furnish these patients with their test reports.

To help offset compliance costs, labs may charge a reasonable, cost-based fee. If the patient requests that the copy be mailed, the fee may include only the cost of copying (including supplies and labor) and postage. If the patient asks for a summary or explanation of the information, the fee may be charged for preparing it but may not include any costs associated with searching for and retrieving the information requested.

 © 2013 Kennedy Information, LLC, A Bloomberg BNA Business, 800-531-1026. All Rights Reserved. Reproduction Prohibited by Law.

Battle Continues Over MAC Award to Noridian

Two Medicare Administrative Contractors (MACs) are continuing their fight against the decision by the Centers for Medicare and Medicaid Services (CMS) to award a claims processing and payment contract for Jurisdiction E to Noridian Administrative Services (Fargo, N.D.)

This jurisdiction covers California, Nevada, and Hawaii, as well as the U.S. territories of American Samoa, Guam, and the Northern Mariana Islands. It includes more than 3.5 million fee-for-service beneficiaries and serves some 500 hospitals and 86,500 physicians. The workload comprises approximately 8.9 percent of the national Medicare A and B fee-for-service claims volume.

The probable cost for Noridian's proposal was $373 million, while those from Palmetto and CGS came in at $371 million and $408 million, respectively. The GAO protest decision is at www.gao.gov/assets/660/652332.pdf.

Protests filed by Palmetto GBA, which previously held the contract, and CGS Administrators LLC were denied by the Goverment Accountability Office, which concluded that Noridian's noncost factors were superior and consistent with CMS's evaluation scheme. Rebuffed by the GAO, Palmetto and CGS filed a complaint with the U.S. Court of Federal Claims, which is reviewing the case. Palmetto will continue to process benefit claims for Jurisdiction E until the review is completed.

Upcoming G2 Events

Webinar (2 p.m. – 3:30 p.m. Eastern)

March 20
Pathology Survival Guide: Opportunities for Growth in an Era of Reduced Reimbursement
Featured speaker:Barry Portugal, President, Health Care Development Services Inc.
Dan Angress, Chief Commercial Officer, PathCentral
www.G2Intelligence.com/88305SurvivalGuide

Conferences

May 16
Lab Contracting Workshop: How to Master Changing Market Realities in Dealing with Payers
Westin Atlanta Airport
Atlanta
www.G2Intelligence.com/ContractingWorkshop

June 12-14
MDx Next 2013
Gaining Ground in Molecular Testing and Genomic Medicine
Westin Las Vegas Hotel Casino and Spa
Las Vegas
www.mdxconference.com

Oct. 16-18
Lab Institute 2013
Hyatt Regency Crystal City
Arlington, Va.

For more on our newsletters, research reports, other products, and services, visit our Web site, www.G2Intelligence.com.

NIR Subscription Order/Renewal Form

❑ *YES*, enter my one-year (22-issues) subscription to the *National Intelligence Report (NIR)* at the rate of $509/yr. Subscription includes the *NIR* newsletter and electronic access to the current and all back issues. Subscribers outside the U.S. add $100 postal.*

❑ AAB ❑ NILA members qualify for special discount of 25% off or $381.75 (Offer code NIRNI1).

Member # _____ Exp. Date _____

❑ I would like to save $204 with a 2-year subscription to *NIR* for $814.*

❑ Check enclosed (payable to Kennedy Information, LLC)

❑ American Express ❑ VISA ❑ MasterCard CCV Code_____

Card #_____ Exp. Date _____

Cardholder's Signature_____

Name As Appears On Card_____

Name/Title_____

Company/Institution_____

Address_____

City_____ State_____ ZIP_____

Tel_____

E-mail_____

(Required for *NIR* online)

*Total does not include applicable taxes for MD, NJ, OH, WA, and Canada.

Mail to: G2 Intelligence, 17 Church Street, Suite 100, Keene NH 03431-3885 USA.
Or call 800-531-1026 and order via credit card or fax order to +1 603-357-8111

*By purchasing an individual subscription, you expressly agree not to reproduce or redistribute our content without permission, including by making the content available to non-subscribers within your company or elsewhere. For multi-user and firm-wide distribution programs or for copyright permission to republish articles, please contact our licensing department at +1 603-357-8160 or by email at: jping@G2Intelligence.com.

NIR 3/13A

© 2013 Kennedy Information, LLC, A Bloomberg BNA Business, 800-531-1026. All Rights Reserved. Reproduction Prohibited by Law.

Notice: It is a violation of federal copyright law to reproduce all or part of this publication or its contents by any means. The Copyright Act imposes liability of up to $150,000 per issue for such infringement. Information concerning illicit duplication will be gratefully received. Reporting on commercial products herein is to inform readers only and does not constitute an endorsement. *National Intelligence Report* (ISSN 0270-6768) is published by G2 Intelligence, 17 Church Street, Suite 100, Keene NH 03431-3885 USA. Tel: 800-531-1026 or +1 603-357-8101. Fax: +1 603-357-8111. Web site: www.G2Intelligence.com.

Jim Curren, Editor; Kimberly Scott, Managing Editor, kscott@G2Intelligence.com; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, COO and Publisher.

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 800-531-1026.