



# NATIONAL INTELLIGENCE REPORT™

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## INSIDE NIR

CMS divides PT sanctions into 3 categories, limits reach of ban .....1

Hospital proposal provides labs with new opportunities to be value partners .....1

Joint Commission clarifies stance on IQCP.....3

Exchange of health information growing.....4

CAP seeks clarification of direct billing in Pennsylvania.....8

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## CMS Divides PT Sanctions Into 3 Categories, Limits Reach of Ban

The Centers for Medicare and Medicaid Services (CMS) has finalized a proposal to divide proficiency testing (PT) sanctions into three categories based on the severity and extent of the violation.

In a final rule published in the May 2 *Federal Register*, the agency uses its authority under the Taking Essential Steps for Testing (TEST) Act of 2012 to amend sanctions under the Clinical Laboratory Improvement Amendments (CLIA). The TEST Act gave CMS discretion to substitute intermediate or alternative sanctions in cases of intentional PT referral.

CLIA regulations required labs conducting moderate- or high-complexity testing to enroll in an approved PT program that covers all of the specialties and subspecialties for which the laboratory is certified. As of June 2013, there were 239,922 CLIA-certified laboratories. Of those, 35,035 are required to enroll in a PT program approved by the Department of Health and Human Services (HHS).

*Continued on p. 5*

## Hospital Proposal Provides Labs With New Opportunities to Be Value Partners

Clinical laboratories may have new opportunities to partner with and provide added value to hospitals under a new Medicare proposal for hospital inpatients.

On April 30, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule that would update fiscal year (FY) 2015 Medicare payment policies and rates for inpatient stays at general acute-care and long-term care hospitals. The rule was published in the May 2 *Federal Register*.

The rule's most significant changes are payment provisions intended to improve the quality of hospital care that reduce payment for readmissions and hospital-acquired conditions (HACs). The rule also includes proposed changes to the Hospital Inpatient Quality Reporting (Hospital IQR) program.

Laboratories looking to increase their value to hospitals should see this as an opportunity to help hospitals reduce readmissions and HACs. As discussed in G2 Intelligence's research report, *Creating a Value-Driven*

*Continued on p. 2*



### Upcoming G2 Conferences

May 22, 2014

**New Compliance Red Flags for Labs: How to Minimize Legal Risks in an Evolving Market**

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[www.G2Intelligence.com/RedFlags](http://www.G2Intelligence.com/RedFlags)

June 11-13, 2014

**MDx NEXT: Molecular Diagnostics at the Crossroads: Innovation in the Face of a Reimbursement Crunch**

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Baltimore

[www.MDxconference.com](http://www.MDxconference.com)

## **Hospital Proposal Provides Labs With New Opportunities**, from p. 1

*Laboratory: Opportunities in the New Marketplace*, molecular tests for HACs have been shown to control infection rates and thereby improve outcomes and lower costs.

Private payers also are putting pressure on hospitals to reduce readmissions and HACs, thereby lowering overall cost of patient care. As hospitals face potential reductions in payment, they will look to laboratories to help improve outcomes and reduce costs.

Key provisions of the proposed rule, and areas where labs can play an important role as a value partner, are discussed below.

**Hospital Readmissions Reduction Program.** The maximum reduction in payments under the Hospital Readmissions Reduction Program will increase from 2 percent to 3 percent as required by law. For FY 2015, CMS proposes to assess hospitals' readmissions penalties using five readmissions measures endorsed by the National Quality Forum. Already, CMS estimates that hospital readmissions in Medicare declined by a total of 150,000 from January 2012 through December 2013.

**Hospital-Acquired Condition Reduction Program.** CMS proposes to implement the Affordable Care Act's Hospital Acquired Condition Reduction Program. Beginning in FY 2015, hospitals scoring in the top quartile for the rate of HACs (i.e.,

those with the poorest performance) will have their Medicare inpatient payments reduced by 1 percent. This new program builds on the progress in this area achieved through the existing HAC program, which is currently saving approximately \$25 million annually by reducing Medicare payments when certain conditions that are reasonably preventable are acquired in the hospital.

**Quality Reporting Programs.** The proposed rule would revise measures for the Hospital IQR, Long-

Term Care Hospital Quality Reporting, and PPS-Exempt Cancer Hospital Quality Reporting Programs. CMS proposes to align for 2015 and 2016 the reporting and submission timelines for clinical quality measures for the Medicare Electronic Health Record Incentive Program with the reporting and submission timelines of the Hospital IQR program.

## **Lab Can Address Gaps**

According to research by G2 Intelligence, there are huge opportunities for laboratories to assist hospitals in controlling potentially avoidable complications (PACs). A study conducted using the Prometheus Payment Model, which details the cost of PACs for 21 conditions and procedures, found that PACs comprise anywhere from 20 percent to 50 percent of health care costs.

Using advanced decision support, personalized diagnostics and risk guidance, and lab informatics, laboratories and pathologists can reduce these addressable PAC costs by 30 percent, thus generating 30 percent of a health system's value, says Eleanor Herriman, director of advisory services for G2 Intelligence.

For example, earlier diagnosis of sepsis using rapid molecular diagnostic testing can result in savings of \$5 million to \$23 million, depending on hospital size, according to the study. Testing decision support for hyponatremia can reduce avoidable costs by an estimated 42 percent, which represents \$2 million to \$3 million in annual savings for a midsized hospital.

*"As Medicare continues to move hospitals toward value-based payment, laboratorians should not miss the multiple opportunities to utilize their information and tools to assist hospitals in improving clinical performance and thereby avoiding these penalties."*

—Eleanor Herriman,  
Director of Advisory Services,  
G2 Intelligence

“As Medicare continues to move hospitals toward value-based payment, laboratorians should not miss the multiple opportunities to utilize their information and tools to assist hospitals in improving clinical performance and thereby avoiding these penalties,” says Herriman.

### Pricing Transparency

The inpatient proposed rule also would require hospitals to release a standard list of prices for their medical services, including prices for laboratory services. Instituted as part of the Affordable Care Act (ACA), the requirement can also be fulfilled if hospitals allow the public access to the data after an inquiry.

The ACA contains several policies to encourage greater price transparency in health care. Hospital pricing can vary widely, even within the same geographic area. As consumers are now shouldering a greater proportion of their health care costs, many want actual pricing information on what services will cost.

According to CMS, hospitals can either make public a list of their standard charges or their policies for allowing the public to view a list of those charges in response to an inquiry. The proposal encourages hospitals to undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain at the hospital and to enable patients to compare charges for similar services across hospitals.

*Takeaway: Laboratories have an opportunity to provide added value to their hospital partners by helping them reduce readmissions and hospital-acquired infections. Hospitals are looking to labs to assist them in meeting quality goals as mandated by both federal and private payers.* 

## Joint Commission Clarifies Stance on IQCP

The Joint Commission has published a list of frequently asked questions (FAQs) to address its expectations related to the Individualized Quality Control Plan (IQCP) for clinical laboratories.

On Jan. 1, 2014, the Centers for Medicare and Medicaid Services (CMS) began a two-year education and transition period for the IQCP, a new quality control option for clinical laboratories. The IQCP Interpretive Guidelines outline a risk assessment model for establishing a quality control frequency that will replace the current Equivalent Quality Control (EQC). EQC must be phased out by Jan. 1, 2016.

To assess the CMS revisions, the Joint Commission changed the Quality System Assessment for Nonwaived Testing (QSA) chapter of the Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing. Note 2 was added to the Rationale for Standard QSA (02.04.01) to explain the commission’s expectations during the education and transition period and was communicated in the March 2014 *Joint Commission Perspectives*. However, this note raised more questions. To minimize confusion, Note 2 has been removed and the commission has issued a FAQ to answer additional questions (see below).

### FAQs on IQCP

***Must my laboratory continue to perform quality control for any test system(s) being considered for an IQCP?***

During CMS’s IQCP education and transition period, laboratories must continue

to maintain compliance with existing Joint Commission requirements and Clinical Laboratory Improvement Amendments (CLIA) regulations related to quality control for all test systems.

***What if my laboratory fails to perform quality control for any test system under consideration for an IQCP?***

Failure to maintain compliance with Joint Commission requirements or existing CLIA regulations related to quality control will result in citation for quality control noncompliance.

***Does the education and transition period apply to all quality control for all test systems?***

The education and transition period applies only to test system(s) being investigated by the laboratory for inclusion in an IQCP.

***Takeaway: Laboratories must continue to comply with existing requirements for quality control during CMS's education and transition period for IQCP.*** 

## Exchange of Health Information Growing

**T**he number of acute-care hospitals that electronically exchanged health information with a health care provider outside their information network reached an all-time high in 2013, according to data released by the Office of the National Coordinator (ONC) for Health Information Technology May 5.

More than 60 percent of nonfederal acute-care hospitals electronically exchanged some kind of patient health information with a health care provider outside their network in 2013, a 4 percent increase compared with exchange rates in 2012, according to the ONC data. Additionally, 40 percent of hospitals exchanged health data with another hospital in 2013, also a 4 percent increase over 2012 rates.

The type of information exchange included laboratory results, radiology reports, clinical care summaries, and patient medication histories.

Federal lawmakers and oversight agencies have been critical of the Department of Health and Human Services' progress to date on advancing interoperability among health care providers and hospitals. In March, the Government Accountability Office published a report that found that many providers are still struggling to exchange data with health systems outside their vendor networks despite federal incentives to adopt electronic health records.

The data released May 5 were based on a joint ONC-American Hospital Association survey of 2,655 hospital executives conducted between November 2013 and February 2014.

The types of information acute-care hospitals were capable of exchanging also expanded significantly between 2008 and 2013, according to the ONC data. Hospital exchange of laboratory results, radiology reports, clinical care summaries, and patient medication histories all expanded between 2008 and 2013, according to the data. In 2013, 57 percent of acute-care hospitals exchanged laboratory results, up from 35 percent in 2008. In 2013, 55 percent of acute-care hospitals exchanged radiology reports, up from 37 percent in 2008.

***Takeaway: Hospitals and other health care providers are doing a better job of exchanging health information, including laboratory results, with each other, but there's still a long way to go.*** 

## **CMS Divides PT Sanctions Into 3 Categories**, *from p. 1*

CMS views proficiency testing as a valuable tool that labs can use to verify the accuracy and reliability of their testing. During PT, an HHS-approved PT program sends samples to be tested by a laboratory on a scheduled basis. After testing the PT samples, the lab reports its results back to the PT program for scoring. As there is no on-site, external proctor for PT testing in a laboratory, the testing relies in large part on an honor system. For each PT event, labs are required to attest that PT samples are tested in the same manner as patient specimens are tested.

Any lab that intentionally refers its PT samples to another laboratory for analysis risks having its certification revoked for at least one year, with the owner prohibited from owning or operating another laboratory for two years.

*Under this final rule, CMS has amended the CLIA regulations so that a lab “may” (as opposed to “must”) have its CLIA certification revoked when the agency determines that PT samples were intentionally referred to another laboratory. CMS has established three different sanction categories.*

While the phrase “intentionally referred” has not been defined by statute or regulations, CMS has consistently interpreted the phrase to mean “general intent, as in intention to act.” Thus, any lab that referred a PT sample to another lab automatically would face the most severe penalties.

Under this final rule, CMS has amended the CLIA regulations so that a lab “may” (as opposed to “must”) have its CLIA certification revoked when the agency determines that PT samples were intentionally referred to another laboratory. CMS has established three different sanction categories.

### **Category 1**

The first category is for the most serious, egregious violations, encompassing cases of repeat PT referral or cases where a laboratory reports another lab’s test results as its own. In such cases, CMS does not believe that alternative sanctions alone would be appropriate. Therefore, the agency will revoke the CLIA certificate for at least one year, ban the owner or operator from owning or operating a CLIA-certified lab for at least one year, and possibly impose a civil money penalty (CMP).

A “repeat proficiency testing referral” is defined as “a second instance in which a proficiency testing sample, or a portion of a sample, is referred, for any reason, to another laboratory for analysis prior to the laboratory’s proficiency testing program event cut-off date within the period of time encompassing the two prior survey cycles (including initial certification, recertification, or the equivalent for laboratories surveyed by an approved accreditation organization).”

### **Category 2**

Under a second category of sanctions, a CLIA certificate would be suspended or limited (rather than revoked) in combination with the imposition of alternative sanctions. This approach would be used in instances in which a lab refers PT samples to a lab that operates under a different CLIA number before the PT event close date and, while the lab reports its own results to the PT program, it receives results from the second lab prior to the event close date.

Such a referral situation would allow the referring laboratory an opportunity to confirm, check, or change its results prior to reporting its results to the PT program.

If, upon investigation, surveyors determine that the referral does not constitute a repeat PT referral, CMS would suspend or limit the CLIA certificate for less than one year rather than revoke it and would impose alternative sanctions. An alternative sanction would always include required training of staff.

A suspension of the CLIA certificate means that no testing of human specimens for health care purposes may be performed by that laboratory during the period of suspension. In such cases, the owner or operator typically contracts with another operator to run the lab under the contracted laboratory's CLIA certificate. In contrast to a revocation of the CLIA certificate and its accompanying ban on the owner and operator, suspension usually applied only to the individual laboratory in question rather than all laboratories that are under the control of the owner or operator.

A limitation of the CLIA certificate means that the lab is not permitted to perform testing or to bill Medicare or Medicaid for lab work in the specialty or subspecialty that has been limited but may continue to conduct all other testing under its own CLIA certificate.

In determining whether to suspend or limit the CLIA certificate, CMS would examine the extent of the PT referral practice, as well as its duration. If surveyors determine that in the previous two survey cycles there were prior PT referrals that occurred but were not cited by CMS, then the CLIA certificate would always be suspended rather than just limited. The duration of the suspension would reflect the number of samples referred, the period of time the referrals had been occurring, the extent of the practice, and other criteria.

In the second category, alternative sanctions also would be applied in addition to the principal sanctions. At a minimum, alternative sanctions would include a CMP as well as a directed plan of correction. In addition, if the CLIA certificate is suspended, CMS would impose state on-site monitoring of the laboratory.

### Category 3

A third category of sanctions will be applied to those PT referral scenarios in which the referring laboratory does not receive test results prior to the event cutoff date from another laboratory as a result of the PT referrals. In such cases, the lab will be required to pay a CMP as well as comply with a directed plan of correction, which would always include training of staff.

#### Cost and Benefits

CMS estimates that only six cases per year would actually qualify for alternative sanctions. Based on experience with laboratories that engaged in PT referrals in the past, the agency estimates that the average cost incurred by labs that had their CLIA certificate revoked was \$578,000 per laboratory.

The cost of alternative sanctions, based on comparable violations, is estimated at \$150,000 per laboratory. With net average savings per affected certificate holder of about \$428,000, CMS projects that the aggregate annual savings would be approximately \$2.6 million per year (\$428,000 times six labs).

For example, a laboratory may place PT samples in an area where other patient specimens are picked up by courier to take to a reference laboratory. The reference laboratory courier may take the PT samples along with the patients' specimens. The lab personnel notice that the PT samples are missing and contact the reference lab to inquire if they have received the PT samples along with the patients' specimens. The reference lab is instructed to discard the PT samples and not test them since they were picked up in error.

In this case, the “referring” lab realized the error, contacted the receiving lab, and did not receive results back for any of the PT samples. In this scenario, CMS would impose only alternative sanctions.

## Waived Labs, ‘Intentional’ Referral

In responding to comments submitted to the Sept. 23, 2013, proposed rule, CMS notes that the rule does apply to waived laboratories that participate in PT. The agency also has proposed an exception to its longstanding interpretation of “intentionally refers” in a separate rule. Under that proposal, a referral would not be considered “intentional” if the investigation revealed that PT samples were sent to another lab for

*CMS is adding a provision to limit the reach of the owner ban for certain labs under the same ownership as the revoked laboratory if CMS finds, after a review, that patients would not be at risk if the lab were exempted from the ban and there is no evidence that a lab to be exempted from the ban participated in or was complicit in the PT referral. However, any lab of the owner that received a PT sample from another lab and failed to report such receipt to CMS may not be exempted from the owner ban.*

reflex or confirmatory testing, the referral is not a repeat PT referral, and the referral occurred while personnel were acting in full conformance with the laboratory’s written, legally accurate, and adequate standard operating procedures.

## Limit on Reach of Ban

CMS also responded to concerns that a mandatory one-year prohibition for owners that applies to all laboratories of the owner would not be reasonable for a large health system that owns a large number of laboratories in many

locations. Commenters suggested that the one-year ban for the owner should be limited to the single laboratory where the PT referral occurred.

The agency notes that it is incumbent upon labs to organize in a manner that allows them to mitigate circumstances so that when one or more labs are sanctioned, the rest of the lab network is not unduly impacted. However, CMS also recognizes that there are benefits to large health systems organizing in ways to promote efficiency of care with the least cost to patients and says it agrees that there should be some discretion in the regulation to allow for flexibility in the mandatory one-year ban against owners of laboratories that would create access issues in the communities in which they serve.

As such, CMS is adding a provision to limit the reach of the owner ban for certain labs under the same ownership as the revoked laboratory if CMS finds, after a review, that patients would not be at risk if the lab were exempted from the ban and there is no evidence that a lab to be exempted from the ban participated in or was complicit in the PT referral. However, any lab of the owner that received a PT sample from another lab and failed to report such receipt to CMS may not be exempted from the owner ban.

In assessing whether patients would potentially be at risk if the laboratory would be exempted from the ban, CMS will consider factors including, but not limited to, the following: the extent to which staff of the lab that may be exempted from the owner ban have been adequately trained and will promptly have such training reinforced regarding PT, the history of compliance with the CLIA regulations, evidence of any systemic quality issues for the lab that seeks to be exempted, and the potential for access-to-care problems for patients if the lab was not granted an exemption.

***Takeaway: CMS will use more enforcement discretion in determining what sanctions to impose in cases where a laboratory violates the prohibition of proficiency testing referrals. Sanctions will be divided into three separate categories.*** 

## CAP Seeks Clarification of Direct Billing in Pennsylvania

The College of American Pathologists (CAP) is urging the Centers for Medicare and Medicaid Services (CMS) to ensure compliance in Pennsylvania on current federal prohibitions on reassignment related to a proposed Medicaid expansion waiver for the state.

Pennsylvania has proposed to expand Medicaid enrollment under an operational plan now used by Iowa and Arkansas. According to CAP, the plan is known as the “private option,” in which premium assistance is offered to individuals who qualify under Medicaid expansion income eligibility criteria as provided for under the Affordable Care Act.

The premium assistance program utilizes qualified health plans in the state health insurance exchange to deliver purchased coverage benefits outside the traditional operation of the Medicaid program. Iowa and Arkansas both received approval of their respective programs in 2013.

CAP is concerned about use of the waiver to usurp requirements for Medicaid programs, specifically requirements for direct billing by providers of health care services, including pathology and laboratory services.

“The explicit federal prohibition on reassignment of Medicaid claims, in particular, prevents numerous business and medical practice abuse in the provision of pathology and laboratory services,” wrote Gene Herbek, M.D., CAP president, in an April 10 letter to CMS. “It is our judgment that such abuses in pathology/laboratory services are engendered when claims are reassigned by the provider of the service to the ordering clinician. These abuses include fee-splitting, self-referral, markups, kickbacks, and rebates that all have potential to incentivize the unnecessary provision of pathology/laboratory services by ordering clinicians who perform no component of the service.”

CAP took no position on the agency’s approval of the waiver other than expressing concern on the need to ensure compliance with the current federal prohibition on reassignment.

*Takeaway: The College of American Pathologists wants to ensure that approval of a Medicaid waiver in Pennsylvania ensures that there will be no reassignment of state Medicaid claims and requires payment to the provider of the service.* 

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