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Hospital Star Ratings: 5-Star Hospitals are Few and Far Between

As of April 16, consumers can go to the Centers for Medicare and Medicaid Services (CMS) Hospital Compare website and select up to three hospitals to get their star rating and other comparative data to help them select a hospital for non-emergency surgeries or other procedures. Of the 3,553 hospitals reporting data, 561 (approximately 7 percent) received a 5-star rating. The star ratings are currently based on Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) data gathered through a standardized survey tool administered to random patients throughout the year. Hospitals must have at least 100 completed surveys in a 12-month period to receive a star rating. CMS, working with Yale University, plans to incorporate all of the data reported through Hospital Compare to make up the star rating as soon as 2016.

Hospital Compare is part of CMS's hospital quality initiative designed to improve quality in hospitals by providing a set of objective, easy-to-understand information on hospital quality from a consumer's perspective. Ideally, as hospitals strive to improve their star rating, their quality will improve also. The data is to be updated quarterly by CMS.

As part of moving the Medicare program to a value-based payment system, the outcomes of patient surveys can affect a hospital's bottom line. At some point, compliance problems may arise in cases where hospitals manipulate data to appear more favorable or an ancillary service, like a laboratory, goes too far in supporting a hospital or physician's quality reporting, resulting in increased reimbursement for the hospital or physician.

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SGR Repeal Emphasizes Move to Value-Based Payments

After a long and winding road, the sustainable growth rate (SGR) is finally part of history and the move to value-based payments has renewed urgency now that the *Medicare Access and CHIP Reauthorization Act of 2015* (Act) has become law. The Act became law April 16, repealing the SGR and establishing the conversion factor updates we detailed in the most recent issue of *National Intelligence Report*: 0.0% for January 1,

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Hospital Star Ratings: 5-Star Hospitals are Few and Far Between, *from page 1*

Part of CMS's Overall Transparency Effort

According to a CMS press release, these are the first ever star ratings for hospitals but not for some of the other categories of public reporting designed to enhance quality and aid consumer choice. The new ratings are part of a U.S. Department of Health and Human Services larger effort to build a health care system that delivers better quality of care, uses health care dollars wisely and results in healthier people. "These star ratings also encourage hospitals and clinicians to strive to continuously improve the patient experience and quality of care delivered to all patients," said Patrick Conway, Acting Principal Deputy Administrator for CMS and Deputy Administrator for Innovation and Quality in the press release announcing the new ratings.

The data compares information about the patient experience, as reported in the HCAHPS consumer satisfaction surveys in 11 patient satisfaction categories. Star ratings and comparative data are not confined to hospitals. There are also comparative data and/or star ratings on nursing homes, large physician practices, dialysis facilities, Medicare Advantage health plans and home health. The hospital rating website allows the user to view data for a single hospital or compare information on up to three hospitals in the patient's service area selected by zip code or state.

The website provides general information for the hospital such as the address, type of hospital, whether it provides emergency services and, surprisingly, whether or not it is able to receive and track laboratory results through the use of a certified electronic health record system. It also asks if the hospital uses a safe surgery checklist. A review of the data being reported reveals that laboratory services play an important role in monitoring quality of hospitals. For instance, in the section on health care associated infections, there are two laboratory-identified events: Methicillin-resistant Staphylococcus Aureus infections and Clostridium difficile (C. diff.) infections.

Star Rating Results for Hospitals

The following is a breakdown of how many hospitals received each star rating.

★
1 star: 101 hospitals (3 percent)

★★
2 stars: 582 hospitals (15 percent)

★★★
3 stars: 1,414 hospitals (40 percent)

★★★★
4 stars: 1,205 hospitals (34 percent)

★★★★★
5 stars: 251 hospitals (7 percent)

The HCAHPS star ratings will be updated each quarter, according to CMS.

The 11 measures of patient satisfaction include:

- How well did doctors and nurses communicate with the patient;
- How long did it take to get help after asking for it;
- How well pain was controlled;
- Cleanliness of the hospital room and the facility overall;
- Whether or not the patient received discharge instructions and if he or she understood them; and
- The percentage of patients rating the hospital as a 9 or 10 on a scale of 0 to 10 and whether they'd recommend the hospital to others.

Users can review aggregate comparisons such as averages in the country and can select the format displaying the data, such as a chart or graphical representation.

Adding the star ratings summary data makes it easier for consumers to use information about hospital quality of care and the service a patient can expect and it has the added advantage that it is a common method of rating products and services.

Hospitals and Others Point Out Flaws

Not everyone is a fan of the consumer-based star rating system of comparing hospital quality and service data. The American Hospital Association (AHA), through its publication *Hospital and Health Networks Daily*, warns that the use of a single overall rating has some risks, quoting Akin Demehin, AHA senior associate director of policy: "There's a risk of oversimplifying the complexity of quality care or misinterpreting what is important to a particular patient, especially since patients seek care for many different reasons."

The risks and benefits of transparency in health care areas like quality, prices, outcomes and other categories are being closely studied by many. Some fear that a consumer-focused star rating system places too much weight on the patient's perspective rather than other statistically valid information. Others argue that star ratings are something consumers are familiar with and place value in, while other rating systems are too complex and difficult for patients to understand.

Hospital compare is another tool made available to consumers to help make better decisions about the care they receive and who provides that care. This information becomes more important than ever as patients are being asked to pay for more of their care out of their own pocket and take more control over their own health. Adding the star ratings summary data makes it easier for consumers to use information about hospital quality of care and the service a patient can expect; it has the added advantage that it is a common method of rating products and services.

Takeaway: Laboratories and the data they own could have a significant role in quality measurement, affecting payments positively or negatively.

OIG & Industry Leaders Collaborate on Guidance Regarding Compliance Oversight

On April 20, the U.S. Department of Health and Human Services' Office of Inspector General (OIG) released a compliance guidance document created through the joint efforts of the OIG, the American Health Lawyers Association (AHLA), the Association of Healthcare Internal Auditors (AHIA) and the Health Care Compliance Association (HCCA). The document's purpose is to assist governing boards of health care entities in their oversight of compliance plans.

While the intended audience is governing boards, the document offers anyone with a compliance role insight and ideas for improving compliance within their laboratory or other health care organization. According to a press release, the 19-page document is an educational resource that will benefit compliance officers, auditors and legal counsel in addition to the boards to which they report. It's intended to provide practical ideas, tools and tips that can be adapted for organizations of all sizes. The introduction explains: "A critical element of effective oversight is the process of asking the right questions of management to determine the adequacy and effectiveness of the organization's compliance program, as well as the performance of those who develop and execute that program and to make compliance a responsibility for

all levels of management." The guidance also explains the interrelationship between and individual importance of the following compliance-related functions: compliance, legal, internal audit, human resources, and quality improvement.

The areas of focus addressed in the guidance include: expectations for board oversight, compliance roles, reporting to the board, identifying and auditing risk areas, and encouraging accountability. The document recommends using existing guidance materials available to boards and compliance professionals as "benchmarks" for evaluating the effectiveness of their compliance plans—including the Federal Sentencing Guidelines, OIG compliance program guidance and Corporate Integrity Agreements (CIA). While a CIA is an agreement that entities enter into once they have already gotten in trouble, the measures negotiated into these agreements "may be helpful resources for Boards seeking to evaluate their organizations' compliance programs."

It's worth noting that among the top risk areas highlighted, the first issue mentioned is referral relationships and arrangements—an issue of significant relevance to laboratories particularly in light of last year's fraud alert and current enforcement efforts targeting such relationships.

Suggestions for facilitating management's compliance reporting directly to governing boards include use of dashboards and executive sessions. The document also discusses methods for keeping tabs on current compliance risks, including sources such as compliance hotlines and internal audits as well as "professional organization publications, OIG-issued guidance, consultants, competitors, or news media." "When failures or problems in similar organizations are publicized, Board members should ask their own management teams whether there are controls and processes in place to reduce the risk of, and to identify, similar misconduct or issues within their organizations," the document advises.

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Highlighting the potential for "new incentives and compliance risks" created by current health care reform efforts, the guidance notes: "New payment models have also incentivized consolidation among health care providers and more employment and contractual relationships (e.g., between hospitals and physicians)." Laboratory compliance professionals should heed the guidance's suggestion that "Boards of entities that have financial relationships with referral sources or recipients should ask how their organizations are reviewing these arrangements for compliance with the physician self-referral (Stark) and anti-kickback laws."

Increasing transparency was also highlighted, with the availability of data from CMS on quality measures, payment data and the Sunshine rule providing public access to more information than ever before. The OIG and its collaborators encourage boards to "consider all the beneficial uses of this newly available information" for evaluating compliance and establishing benchmarks. Finally, boards are urged to consider and employ measures to incentivize compliant behavior and create a culture of compliance, while conducting self-evaluations and, when necessary, self-reporting non-compliance and repaying overpayments.

The resource, "Practical Guidance for Health Care Governing Boards on Compliance Oversight," can be found on the OIG's website.

Takeaway: A new guidance document provides not just governing boards but all individuals involved in compliance with helpful tips for improving compliance, evaluating effectiveness and adapting compliance plans to a changing health care environment focused on quality and value. G2

EEOC Proposes Rules for Employer Wellness Programs to Avoid Potential Discrimination

As the focus on quality and value intensifies, wellness programs will no doubt play an integral role in the health care system. We reported last year in our sister publication *Laboratory Industry Report*, that it's still too early to tell if growth in wellness programs will be a significant revenue opportunity for laboratories but laboratory testing is clearly an integral part of identifying, monitoring and managing health conditions such as diabetes, high cholesterol and others that are a focus of wellness efforts. The 2014 Employer Health Benefits Survey from the Henry J. Kaiser Family Foundation reports that "[v]irtually all large employers (200 or more workers) and most smaller employers offer at least one wellness program." Furthermore, the survey indicated that 36% of large employers and 8% of small employers offering health benefits and wellness programs also include some kind of financial incentives to encourage employee participation in these programs, such as lower premium contribution or deductibles, gift cards or cash.

The Equal Employment Opportunity Commission (EEOC) is concerned that employer wellness programs including participation incentives and medical examinations or inquiries about employee's disabilities could lead to discrimination against employees. So the EEOC issued a proposed rule addressing incentives offered "to encourage employees to participate in wellness programs that include disability-related inquiries and/or medical examinations." The proposed rule amends regulations and interpretive guidance implementing the Americans with Disabilities Act (ADA).

Laboratories should be interested in these guidelines not just for their impact on participation in wellness efforts that could potentially increase demand for laboratory services but also because laboratories are employers too and may be offering these programs.

Noting that HIPAA requirements prevent employers from offering incentives so great that they effectively deny coverage or impose too great a penalty on individuals who don't meet certain health standards, the EEOC said that HIPAA doesn't limit the information employers can request concerning medical examinations and disabilities under such programs. Thus, the EEOC's proposed rule requires:

1. Wellness programs that include disability-related inquiries or medical exams "must be reasonably designed to promote health or prevent disease"—that is, it must have "a reasonable chance of improving the health of, or preventing disease in, participating employees, and it is not overly burdensome, is not a subterfuge for violating the ADA or other laws prohibiting employment

discrimination, and is not highly suspect in the method chosen to promote health or prevent disease."

2. To be considered voluntary, an employer offering a wellness program including disability-related inquiries or medical exams must not require participation, deny coverage in group health plans or benefit packages in such plans for lack of participation, or take adverse employment action or retaliate against or intimidate or threaten employees who do not participate or who don't achieve certain health results. Employers must also provide notice of the medical information that will be collected, who will get the information, how it will be used or disclosed, restrictions on disclosure, and how it will be protected from improper disclosure.
3. Incentives for participation in a wellness program that is part of a group health plan and include "disability-related inquiries" or medical exams can't exceed 30 percent of the total cost of employee-only coverage or the plan won't be considered voluntary.
4. Except for certain purposes such as administering a health plan, medical information should be provided in aggregate and not identify the employee.

Takeaway: Workplace wellness programs continue to be a tool for improving health care but the EEOC is concerned they not be used in ways that adversely affect employee/patients. G2

Medicare Coverage Proposed for HPV Screenings

Medicare beneficiaries between the ages of 30 and 65 could be tested for Human Papillomavirus (HPV) every five years, "in conjunction with the Pap Smear test," under a newly proposed coverage decision from the Centers for Medicare and Medicaid Services (CMS). CMS issued the proposed decision memorandum April 16, 2015, with a 30-day public comment period.

Currently, Medicare doesn't provide reimbursement for HPV testing and only permits Pap tests for women every 12 or 24 months, depending on risk factors.

CMS reports that cervical cancer "is almost always caused by a sexually transmitted infection with human papillomavirus (HPV)." HPV is also linked to other cancers such as anal, vaginal, penile, vulvar and oropharyngeal cancers. The new screening recommendation tracks the recommendation of the U.S. Preventive Services Task Force (USPSTF) which recommends Pap smears in combination with HPV testing every five years for women between 30 and 65 years old. USPSTF gives this recommendation a Grade A, meaning "[t]here is high certainty that the net benefit is substantial."

Currently, Medicare doesn't provide reimbursement for HPV testing and only permits Pap tests for women every 12 or 24 months, depending on risk factors.

The Centers for Disease Control and Prevention reports that HPV "is the most common sexually transmitted infection" with 14 million people becoming infected each year and approximately 79 million Americans currently infected. One type of HPV is credited with causing nearly all cases of cervical cancer, which affects 11 million American women each year.

For both HIV and HPV, infection can occur long before symptoms arise that could alert individuals they are infected.

This coverage expansion follows closely on the heels of Medicare coverage expanded for another sexually transmitted infection — HIV. In January, CMS issued a proposed decision memorandum, soliciting public comment on a proposal to expand coverage to provide screening for the following:

- Up to one annual voluntary screening for individuals between age 15 and 65, regardless of risk;
- Up to one annual voluntary screening for those under age 15 or over 65-years old, if there is increased risk of infection such as those having unprotected intercourse, injection drug users, individuals who had blood transfusions between 1978 and 1985, individuals with new partners or partners who were HIV infected or injection drug users; and
- Up to three voluntary HIV screenings for pregnant women (at time pregnancy is diagnosed, in the third trimester and/or at labor).

Prior to that proposal, Medicare only provided for up to one annual voluntary screening for those at risk of infection and up to three voluntary screenings for pregnant women at the same times as in the proposal. After receiving 16 comments, CMS finalized that coverage decision memorandum on April 13, 2015.

For both HIV and HPV, infection can occur long before symptoms arise that could alert individuals they are infected.

Medicare coverage continues to expand for screening of diseases that lack early symptoms yet have potentially life-threatening consequences in the future if undetected.

SGR Repeal Emphasizes Move to Value-Based Payments, *Continued from bottom of p.1*

2015 through June 30, 2015; 0.5% for July 1 through December 31, 2015; 0.5% for 2016-2019; 0.0% for 2020 to 2025; and for 2026 and thereafter, 0.75% and 0.25% depending on "alternative payment model" participation.

As in prior years, physicians escaped at the last minute some major cuts to reimbursement threatened under the SGR methodology. This time, it's for good: "It's a fix, more than just a Band-Aid," notes Dora L. Hughes, M.D., M.P.H., a senior policy advisor at Sidley Austin and former senior Obama Administration official. "The most important message is that this is a tremendous victory, not just for seniors and all Medicare beneficiaries, but also for the health care providers who care for them," adds Patricia DeLoatche, also a policy advisor at Sidley Austin LLP and former Health Policy Director for Senator Orrin Hatch. "The stability of having ongoing physician payment is really important."

Significance

The new law is a watershed moment in health care reimbursement according to Hughes. She describes the legislation as "transformative," and "just as revolutionary" for physician reimbursement as next-generation sequencing is for research. A recent White House blog celebrating the legislation's enactment notes that Centers for Medicare and Medicaid Services (CMS) actuaries, "estimate that the percent

of Medicare physician payments in payment models that encourage higher quality care would more than double in four years, from 25 percent this year to 60 percent in 2019 as a result of this law."

"By hook or by crook the system is now going to be based on value. . . it becomes more real for those who have not fully engaged or participated in alternative payment models, shining a spotlight on the need for individual physicians and groups to focus on quality of care."

— Dora L. Hughes, M.D., M.P.H.

"This is a significant victory," adds DeLoatche, in particular because of the bipartisan efforts over the course of two years that achieved this success. "The fact that this was passed in a bipartisan manner, by overwhelming margins and signed into law by the President" is reaffirming, says DeLoatche. "I think it speaks volumes."

More Work Ahead

This repeal is not an end, however, but just the start of more hard work for pathologists and other physicians. "There's so much left to come, just in terms of moving the system away from volume to value," adds Hughes. "So celebrate this great moment but on the other hand, this is a marathon and we are only half of the way through in terms of getting where we need to be."

This legislation puts the rubber to the road in terms of the switch to value-based reimbursement. "By hook or by crook the system is now going to be based on value," she says, explaining that "it becomes more real for those who have not fully engaged or participated in alternative payment models, shining a spotlight on the need for individual physicians and groups to focus on quality of care."

The challenge, says Hughes will be "establishing the quality measures for physicians broadly, but understanding that they will need to be tailored for the specialty providers. Those measures could be harder to define, particularly given the range of providers that will be affected." She explains that developing quality measures for reimbursement purposes is more difficult for specialties such as pathology, where the provider doesn't have direct patient contact. "One of the important issues moving forward is that it's important that there is collaboration—with different specialties and understanding the unique challenges that some of these specialties face—just taking time to make sure there is discussion back and forth with these different specialties," adds DeLoatche.

"Truly the devil is in the details on this one," says Hughes. For pathologists, some of the quality measures "will need to be tailored to take into account unique aspects of laboratory medicine. There will be continued effort by laboratories to make sure they aren't adversely impacted by the decisionmaking. [But] for all of the difficulty, this is going to be a welcome challenge for all parties," says Hughes.

Takeaway: Pathologists have once again escaped threatened pay cuts but hard work remains for the adjustment to value-based payment methodologies.

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