



HOSPITAL PEER REVIEW®

YOUR BEST SOURCE FOR ACCREDITATION COMPLIANCE

ACCREDITATION • CREDENTIALING • DISCHARGE PLANNING • MEDICARE COMPLIANCE • PATIENT SAFETY • QI/UR • REIMBURSEMENT

SEPTEMBER 2019

Vol. 44, No. 9; p. 97-108

→ INSIDE

Successful quality improvement projects share some common threads 100

Many hospitals not complying with never events policy. 102

Learn from DOJ guidance on compliance 103

Specialty pharmacy can be quality and revenue boost. 105

Patient watches optimize resources. 106



RELIAS
MEDIA

‘Nudge Unit’ Uses Behavior Design to Improve Quality, Patient Safety

A “nudge unit” at the University of Pennsylvania is helping bridge the gap between the study of human behavior and the practice of medicine, devising ways to improve quality of care and patient safety.

The Penn Medicine Nudge Unit is the first behavioral design team embedded within a health system, so the concept is not widely known in healthcare circles.

The “nudge” refers to subtle changes to the way information is presented that can significantly influence how decisions are made or people behave, explains **Mitesh Patel**, MD, MBA, MS, director of the Penn Medicine Nudge Unit. A nudge unit is a behavioral design team comprised of people with skills in behavioral economics, psychology, and related fields.

That team takes a systematic approach to determining when to use a nudge (a change in a process or structure) to create the desired result, along with exactly how to implement

it and roll it out, Patel says. Nudge units were first developed for use in government. Today, governments around the world employ nudge units to create various changes and improvements, Patel says.

The Penn Medicine Nudge Unit launched in 2016 as the first such program in healthcare. Since then it has launched more than 50 projects in multiple departments at Penn Medicine, and it also offers an annual symposium for other healthcare organizations interested in creating nudge units.

The Penn Medicine Nudge Unit works closely with the Penn Medicine Center for Health Care Innovation, whose goal is to reimagine how Penn Medicine provides medical care, and the University of Pennsylvania Center for Health Incentives and Behavioral Economics (CHIBE), which is a research group that tests how economics can influence health policy.

The unit is conceptually and physically a part of the Penn health

ReliasMedia.com

Financial Disclosure: Author **Greg Freeman**, Editor **Jonathan Springston**, Editor **Jill Drachenberg**, Nurse Planner **Jill A. Winkler**, BSN, RN, MA-ODL, Consulting Editor **Patrice Spath**, MA, RHIT, Editorial Group Manager **Leslie Coplin**, and Accreditations Manager **Amy M. Johnson**, MSN, RN, CPN, report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.



HOSPITAL PEER REVIEW

YOUR BEST SOURCE FOR ACCREDITATION COMPLIANCE

Hospital Peer Review® (ISSN 0149-2632) is published monthly by Relias LLC, 1010 Sync Street, Suite 100, Morrisville, NC 27560-5468. Periodicals postage paid at Morrisville, NC, and additional mailing offices. POSTMASTER: Send address changes to *Hospital Peer Review*, Relias LLC, 1010 Sync Street, Suite 100, Morrisville, NC 27560-5468.

GST registration number: R128870672.

SUBSCRIBER INFORMATION:

Customer Service: (800) 688-2421
customerservice@reliasmmedia.com
ReliasMedia.com

Discounts are available for group subscriptions, multiple copies, site-licenses, or electronic distribution. For pricing information, please contact our Group Account Managers at groups@reliasmmedia.com or (866) 213-0844.

ACCREDITATION:

Relias LLC is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. Contact hours [1.25] will be awarded to participants who meet the criteria for successful completion. California Board of Registered Nursing, Provider CEP#13791.

This activity is valid 36 months from the date of publication.

The target audience for *Hospital Peer Review*® is hospital-based quality professionals and accreditation specialists/coordinators.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

AUTHOR: Greg Freeman

EDITOR: Jonathan Springston

EDITOR: Jill Drachenberg

EDITORIAL GROUP MANAGER: Leslie Coplin

ACCREDITATIONS MANAGER: Amy M. Johnson, MSN, RN, CPN

Copyright© 2019 Relias LLC. All rights reserved. No part of this newsletter may be reproduced in any form or incorporated into any information retrieval system without the written permission of the copyright owner.

system, with a steering committee that includes leadership from IT, clinical care, and behavioral economics. The nudge unit regularly presents findings to the health system CEO, chief innovation officer, and other top executives, Patel says.

“We’re constantly working with different departments. We have a lot of active projects and a team of about 20 people that includes project managers, research coordinators, and data analysts,” Patel says. “But we also have partners in every clinical specialty. For example, we have an attending in cardiology who leads all our cardiology projects, and we have two oncology fellows who are leading a couple projects in cancer.”

The Penn Medicine Nudge Unit was launched in part to address a particular problem at Penn Medicine, Patel notes. The health system was ranked last in the region for generic prescribing and wanted to encourage clinicians to prescribe the low-cost alternative more often (when appropriate).

“When people type into the electronic health record, they often think in terms of brand names, so they type in Lipitor. Or, if a patient comes in and asks about a drug they need and you search for it, the first one that came up was the brand name, with the generics listed at the bottom,” Patel says. “It nudged you to select the brand name because everyone is in a hurry and typing in the drug orders quickly.”

Patel’s team changed the electronic health record so that generics became the default choice. The clinician was required to opt out of that choice to prescribe the brand name medication.

“Whether you wrote the order as Lipitor or the generic atorvastatin, it would go to the pharmacy as the generic, unless you wrote it for

Lipitor and also clicked the box that says ‘dispense as written,’” Patel explains. “We first tested this in a small setting, then rolled it out to all the ambulatory clinics across all specialties in all of Penn Medicine. The generic prescribing rate went from 75% to 99% almost overnight.”

That prescribing rate has been maintained for three years, which brought a savings of \$32 million for just the top 75 most prescribed medications. The beauty of it all was that the change only took about an hour to implement, Patel says.

“It required very little effort for such a big impact. All it took was getting the stakeholders aligned and realizing that the system was set up to make it harder to do the right thing,” he explains. “If we just changed the default, that would have a significant impact on physician behavior.”

Many Successful Projects

Not all nudges are that simple or quick, but the experience showed Penn Medicine the value of such an approach. The nudge unit has seen many other successes since then, such as changing the referral rate to cardiac rehab from 15% to 85% by creating an opt out pathway.

The unit also addressed unnecessary imaging for end-of-life cancer patients, reducing that by half simply by changing the default order sets in the electronic health record.

Other improvements include increasing flu vaccination by 10% and cancer screening by 20%. One project started with a survey of internal medicine and general surgery residents, asking how often they ordered inappropriate tests and why. The nudge unit survey also asked for ways to reduce

inappropriate ordering. More than 80% of those surveyed said they ordered unnecessary tests, with almost 50% saying they did so every day.

The reasons they cited included a lack of transparency about the cost of tests and a healthcare culture that did not encourage or reward restraint when ordering tests. Those reasons were used to begin addressing the way faculty support the more prudent ordering of tests when mentoring residents.

Collaboration Avoids Roadblocks

Of course, simply having an idea for a better way to accomplish a task is not as easy as actually implementing it. Lots of quality improvement professionals offer suggestions for these kinds of changes, but adoption is not so easy.

What makes a nudge unit effective? According to Patel, it takes a collaborative approach based on data and research, rather than one person going to another department and telling them to change something.

“The steering committee with leaders from all fields in the health system work with experts in economics and behavioral science. All our ideas are vetted through them first,” Patel says. “Most of our ideas come from frontline clinicians. We get ideas from executive leadership about projects and goals they want us to work on. We also come up with our own ideas.”

In vetting the ideas, the steering committee determines if the issue is addressed within the health system already and whether the change aligns with the goals and needs of the system, Patel says. If the project is deemed appropriate for the nudge

unit, analysts are assigned, and team members work with the right clinical leaders to implement the change.

“It’s really a systematic, structured group approach, rather than thinking about how to do this ad hoc. That’s what most health systems do and what we were doing before our nudge unit,” Patel says. “The steering committee helps prioritize projects and directs us to the right people to work with. We typically will set up a six-month timeline to get all the stakeholders aligned and decided if it’s a good project to continue.”

Stakeholders Must Be on Board

A fundamental principle is that all stakeholders must be aligned, Patel says. For instance, a project in cardiology will not move forward without support from the division chair.

But the nudge unit also involves frontline clinicians in developing the intervention, Patel notes.

“We’ll either show them mock-ups at the beginning or we’ll have a prototype they can play around with and give us feedback,” he says. “The most effective nudges are the ones embedded in their workflow. Often, in order to make that happen, we have to see them using it in everyday practice. We get top-down and bottom-up support before we roll anything out.”

Aligning stakeholders can be the biggest challenge and what requires the most time, Patel reports. The nudge unit addresses that challenge by focusing mostly on changes that can be supported with national guidelines and accepted best practices.

“Another challenge is with IT. Sometimes, the electronic health record is not set up to do things the

way we want. We may find that it is not possible to set up a default or include a note where we want to,” Patel says.

Full Unit Not Required

Obviously, the Penn State Nudge Unit achieves great improvements, but it is a substantial formal unit within a major health system. Can any of the same tactics be applied on a smaller scale?

“Many people are already tinkering in the electronic health record and the way their communications are designed. Most institutions get started by finding an area of work that is of high importance to the health system and there’s a good opportunity to implement a nudge,” Patel notes. “Some institutions will need help with behavioral economics, and others will need help with implementing the change with IT. Others might face more of a challenge with evaluating the results.”

Penn has developed the Nudge Unit Collaborative to help hospitals learn from the experience of the Penn State Nudge Unit as well as the work of other hospitals. (*More details about the collaborative are available online at: <http://bit.ly/2Mk3xZX>.)*

“It’s a great way to see what has worked at other places and what hasn’t worked,” Patel offers. “When I’m thinking about starting a new program or implementing a nudge at my hospital, I can increase my chances of success by seeing what others have done. You also can get feedback from others about the nudge you’re trying to implement.”

Patel expects to see more nudge units in healthcare soon. “I think what has gotten people’s attention is

how simple, low-cost interventions can have a huge impact on patient care and really help to align goals,” Patel says. “These nudges often make clinicians’ jobs easier because they’re doing workarounds to get the result

they know is right. Nudges are all about making the evidence-based choice the easy choice. I think nudge units are something that will really take off for hospitals and health systems.” ■

SOURCE

- **Mitesh Patel**, MD, MBA, MS, Director, Penn Medicine Nudge Unit, University of Pennsylvania, Philadelphia. Email: mpatel@penndoc.org

Several Common Features Form Foundation of Successful Quality Improvement Initiative

Regardless of the goal of a quality improvement project, most successful initiatives share common threads. These common factors should form the foundation of any quality improvement effort and help tailor how the effort is carried out.

One common thread is including frontline staff all the way through from ideation to design and the pilot project, advises **Jeff Terry**, MBA, FACHE, CEO of Clinical Command Centers with GE Healthcare Partners in Dallas. It is a mistake to try implementing a quality initiative only from the top-down, making frontline staff feel ignored and simply ordered to change their ways.

“Whatever the quality improvement initiative is, when we scale it to the organization it needs the nuance that the frontline will bring to it, and it needs the clear endorsement that comes from having frontline staff engaged in it from the start,” Terry says.

There also must be clear alignment between the project at hand and other quality initiatives in the organization.

“You will sometimes see people rolling their eyes when you announce a new initiative because they think this is just the latest thing we’re supposed to do. They have initiative fatigue,” Terry reports. “The way to address initiative fatigue is with clear alignment of this project with the overall goals of the organization and the other ongoing initiatives so it

appears as a continuation rather than one more thing you’re telling them to do.”

Quality leaders have to work at avoiding initiative fatigue, Terry says. It is easy for frontline staff to feel overwhelmed by quality initiatives that come from different sources and that may sometimes seem redundant, he notes.

“They can feel like they addressed this issue already when another department came in with a new dashboard. They got their numbers up, and they got the pizza party. Now, you’re coming in with something that seems to cover the same ground and asking them get on board with it,” Terry explains. “They don’t have the time or, frankly, the interest to sort it out. If the messages on these quality initiatives aren’t well sorted out, they’re going to pretty quickly check out, push it aside, and go back to their other duties.”

Acknowledge

Extra Work

Remember that any quality initiative amounts to extra work for staff, at least in the beginning when leaders ask them to attend education and training sessions, Terry stresses. It can be helpful to acknowledge that fact, even if one cannot avoid the increased work load. Staff also know that not

all quality initiatives work out (even if leaders ask employees to bet that *this* one will be a winner). Consistency and follow-through are important, Terry recommends. Without it, people will lose faith in the project, becoming reluctant to commit if it does not seem leaders are all in.

“Three months later, are we still talking about it in the same way, with the same leaders behind it? If the answer is yes, people will start to buy in. If the answer is no, they will just wait it out,” Terry says.

Monitoring the impact of a project also is vital. Hospitals are finding ways to use data in real time to drive the impact of an improvement effort, Terry says. “Instead of just using the data to say our trend is up or down, we look at that data and say if we don’t do something now, we’re going to have a real problem in an hour or 24 hours,” he explains. “It’s about using that data in the moment. That’s probably the biggest change in the way quality improvement initiatives are being driven lately.”

Address Executive

Concerns

Most healthcare organizations are consistent in their focus on cost, quality, and market performance, says **Julie Cerese**, PhD, RN, MSN, group senior vice president, Performance

Management and National Networks, for Vizient, a company based in Irving, TX, that offers healthcare performance improvement assistance.

To increase the likelihood of buy-in and eventual success with the effort, any quality improvement project should address those concerns at least broadly, and sometimes in the specific ways that are relevant to the organization, she says.

“We try to drive cost, quality, and market performance in every project so that we can address the needs of the chief financial officer, the chief operations officer, chief nursing officer, and the chief quality officer,” Cerese says. “This is a very systematic approach to defining the project plan.”

That principle was applied in several quality improvement programs through the Vizient Performance Improvement Collaboratives Program, which has been used in more than 1,300 hospitals to reduce cost, readmissions, and staff turnover, Cerese notes. The collaboratives highlight some of the common factors in successful quality improvement initiatives because they require hospitals to work together toward the same goals, she explains.

Share Data and Experience

In one project, 21 hospitals sought to implement the CDC Guideline for Prescribing Opioids for Chronic Pain, which required better use of standardized prescribing guidelines, more patient monitoring, and the use of electronic medical records (EMRs) to reduce opioid usage. Hospitals focused on optimizing inpatient opioid use and opioid prescribing in the ED while implementing naloxone programs, among other

tactics. Cerese says that the experience highlights another factor of successful quality improvement programs: the willingness to share data and experiences, and to learn from others.

“Organizations come together and join a collaborative because either they have an initiative underway in their organization and they want to learn from others, or they’re at the very beginning of undertaking an initiative and use the format from the collaborative to kick-start their effort,” Cerese says. “A collaborative is a very prescribed effort in that we are asking organizations to develop a charter that defines where your biggest opportunities are, your biggest gaps, where you want to implement change, and how you will measure that success over time.”

Collaborative participants study best practices and develop an implementation plan that should be operationalized quickly, Cerese explains. Members gather every two weeks to discuss implementation progress and exchange ideas. That frequent discussion and feedback is another common thread in successful programs.

“We used to do it monthly, but we increased it to every two weeks. The members told us that monthly was too long to wait for getting back together and evaluating progress,” Cerese reports. “If we do it on a two-week cycle, members stay more attentive in the effort. Over a month, it can kind of fall off your radar.”

Measures of Success Vital

Every project also has measures of success, Cerese says. In an orthopedic collaborative, members are asked to collect detailed data on the percentage of patients receiving opioids in the

first two days postoperatively and after discharge.

“We measure those on an ongoing basis, not just during the collaborative, which can last four to six months,” Cerese says. “We continue to measure because sometimes it takes a little bit longer to take hold of the improvement efforts. A lot of times, these data are embedded in the EMR. Getting that data out of the system can take a little more effort than you expect.” Another recently completed collaborative addressed managing serious illness. The goal was to support patients in their decision-making to meet their goals of care, Cerese says. The collaborative had to avoid jumping right into implementation before knowing the targets, illustrating the need for prioritization with quality improvement.

“We utilized a steering committee of subject matter experts from across the country to determine the best practices and how to implement them. The first strategy was around identifying the patients who needed to have this conversation,” Cerese explains. “We asked members to identify methods to identify patients who needed this attention. Some of the solutions were technological, ways to flag cases based on their presenting condition, but there are lots of other patients who should be included but who don’t have a condition like cancer that might be an obvious flag.”

The collaborative identified patients by asking physicians, “*Would you be surprised if this patient died in the next 12 months?*” The question was suggested in literature regarding the identification of patients with end-of-life concerns; there were data to support its use. The care process is determined in part by the answer to the question, and the collaborative developed guidelines for clinicians to

use for patients who may be facing end-of-life decisions.

“We assembled a checklist of expected processes that should be put in place to guide clinicians in these discussions. Many of the members implemented them in small settings like a nursing unit,” Ceresse notes. “In

one nursing unit, we saw an increase of 53% of the patients who should be having goals-of-care discussions actually having them over a four-month period.” ■

SOURCES

- **Julie Ceresse**, PhD, RN, MSN, Group

Senior Vice President, Performance Management and National Networks, Irving, TX. Email: julie.ceresse@vizientinc.com.

- **Jeff Terry**, MBA, FACHE, CEO, Clinical Command Centers, GE Healthcare Partners, Dallas. Phone: (312) 775-1700.

Many Hospitals Not Complying With Leapfrog Never Events Policy

One-quarter of American hospitals do not meet The Leapfrog Group’s standard for addressing never events, according to a recent report.

The finding is derived from data collected in the 2018 Leapfrog Hospital Survey of more than 2,000 U.S. hospitals. The report calls attention to official hospital policies

for responding to the 29 serious reportable events as identified by The National Quality Forum (NQF). (*The Leapfrog report is available online at: <https://bit.ly/2XhrDKB>. See the story at the bottom of this page for details of the Leapfrog policy on never events.*)

The Leapfrog Hospital Survey first addressed the never event policy in 2007, finding that 53% of hospitals

fully complied with the five best practices in the policy at that time. Compliance hit 79% in 2014 and plateaued there. The Leapfrog Group has since added four more best practices; compliance with all nine is significantly lower.

In 2018, 25.4% of the reporting hospitals failed to meet Leapfrog’s expanded standard. The falloff in compliance was expected because the 2018 survey was the first to ask about all nine current best practices in Leapfrog’s never events policy, says **Erica Mobley**, director of operations for The Leapfrog Group.

“We had seen pretty consistent performance, around 80%, for the past four years. That sounds pretty good, that 80% of hospitals were complying, but this is something that 100% of hospitals should be doing,” Mobley stresses. “We wanted to know what was keeping hospitals from complying with a pretty straightforward policy, doing the right and decent thing that all other industries would hold themselves accountable to doing if they experienced the equivalent of a medical never event.”

The decrease is somewhat understandable because the bar has been raised with the additional requirements, but Mobley says hospitals should strive for full

WHEN A NEVER EVENT OCCURS

The Leapfrog Group asks hospitals to commit to these best practices after a never event:

- Apologize to the patient;
- Report the event;
- Perform a root cause analysis;
- Waive costs directly related to the event;
- Provide a copy of the hospital’s policy on never events to patients and payers upon request;
- Involve patients and families in the root cause analysis when willing and able to participate (added in 2017);
- Inform the patient and family of the action(s) that the hospital will take to prevent future recurrences of similar events based on the findings from the root cause analysis (added in 2017);
- Put a protocol in place to provide support for caregivers involved in never events, and make that protocol known to all caregivers and affiliated clinicians (added in 2017);
- Perform an annual review to ensure compliance with each element of Leapfrog’s Never Events Policy for each never event that occurred (added in 2017). ■

SOURCE: The Leapfrog Group. When hospitals say “I’m sorry.” Available at: <http://bit.ly/2ynC4OS>. Accessed July 29, 2019.

compliance. “It is somewhat disturbing that there are some hospitals that are not willing to make this commitment and take these steps to respond appropriately if the worst happens,” Mobley offers.

Of the nine elements, the one with which the fewest hospitals complied regards performance of an annual review to ensure compliance with the Leapfrog policy, Mobley notes.

“That basically means you have a policy in place. Do you conduct an annual review to make sure you have all those elements? They’re working for you? It’s very straightforward. It’s interesting that’s the one hospitals are having the hardest time with,” Mobley says. “I think I would attribute that to hospitals just not making it a priority. They think

they’ve done the other elements and there’s no need to go back look at it again or worry about it anymore.”

Hospitals also fail to comply with the policy requiring them to make the never events policy available to patient and payers on request. The best practices that are more involved and more challenging to comply with are the ones for which hospitals tend to report higher compliance, Mobley explains.

Leapfrog puts new standards on its survey for a year without reporting results to gauge feedback on particular aspects. The first year of the full never events list revealed some concerns from hospitals, Mobley notes. Some facilities expressed concerns about Leapfrog’s desire to include time components for some of the best

practices, such as requiring them to be performed within 24 or 48 hours. “There was some pretty strong feedback on that with hospitals saying it was not feasible to comply with that time frame in some instances. We removed that component before we put it on the survey that would be publicly reported,” Mobley says. “We aren’t going to lower our standards if hospitals are just choosing not to do something. If there are valid reasons for objecting to something, we will consider that before putting the final version on our survey.” ■

SOURCE

- **Erica Mobley**, Director of Operations, The Leapfrog Group, Washington, DC. Phone: (202) 292-6813.

DOJ Offers Guidance on Compliance Programs

Healthcare professionals involved in compliance programs have new guidance from the Criminal Division of the Department of Justice (DOJ), which recently issued a document that tells white-collar prosecutors how to evaluate compliance programs.

DOJ’s Fraud Section issued similar guidance in February 2017, but this new guidance “seeks to better harmonize the guidance with other department guidance and standards while providing additional context to the multifactor analysis of a company’s compliance program,” the department said in a written statement. (*The full DOJ statement is available at: <http://bit.ly/2MrVzxN>. The updated guidance is available at: <https://bit.ly/2lEphmk>.*)

The 2019 guidance, like the 2017 guidance before it (and guidance from the Office of Inspector General of the

Department of Health and Human Services [HHS-OIG] issued that same year), reflects a practical method for assessment of organizations’ compliance programs, says **Michael B. Lampert**, JD, partner with Ropes & Gray in Boston. The guidance offers specific illustrations of what compliance professionals should focus on.

“For example, the guidance does not ask whether an organization has conducted a risk assessment process, but instead asks what methodology a company’s risk assessment process has followed,” he notes. “Likewise, the guidance asks how companies measure their training effectiveness, not whether there is training, and how a company assesses its employees’ capacity to seek advice [as well as] how and how often a company assesses its culture of compliance.” In brief, the guidance takes a

compliance program’s existence as a given and looks more deeply into how a company’s compliance program really works and how it has evolved over time, Lampert explains. Organizations may assess the specific “how” questions that DOJ has asked.

For healthcare organizations that have operated with a view toward the old HHS-OIG compliance program guidance documents, Lampert says a striking part of the guidance may be where it begins: with risk assessments. “While risk-based construction of a compliance program is not a new concept, and has been part of corporate integrity agreements for a few years now, it is not the starting point of old HHS-OIG guidance, the way that it is for the guidance here,” he says. “Articulation of risk assessment as the first stage for a compliance program, at least at the point of measurement,

is of significance. For healthcare organizations still basing their programs primarily off the HHS-OIG historic guidance, [the new guidance is] potentially a newly articulated area.”

Compliance officers can use the guidance to assess their own programs, Lampert says. The guidance provides very specific tools for measuring program effectiveness. “Like the 2017 DOJ and HHS-OIG guidance, these may be seen as tools

with numerous parts, some of which can be used immediately, and some of which will not be for a particular organization,” Lampert explains.

“But, whatever the point of evolution of a company — and nature of its risks — the guidance provides a menu from which companies’ compliance officers may select. For that matter, it provides a menu from which board members assessing a compliance program’s operations or operators assessing

a potential acquisition target may select.”

No Wholesale Change

Lampert notes that while the 2017 DOJ guidance bound only the Fraud Section, the 2019 version binds the full Criminal Division. The 2019 guidance also reflects a reorganization at DOJ.

“But neither of those observations reflects a wholesale change, and that may be the takeaway. The guidance in some ways broadens, and through some new questions sharpens, but it does not radically change the world from the situation that organizations encountered in 2017,” Lampert offers.

DOJ also recently announced a policy change regarding antitrust compliance, saying the agency will now consider a corporation’s compliance efforts when making charging decisions in a criminal antitrust investigation. *(See the sidebar at left for more on that policy change.)*

Substance Over Form

An overriding theme of the guidance can be summed up in three words: “Substance over form,” says **Geoffrey R. Kaiser**, JD, partner in the Compliance, Investigations & White Collar group with Rivkin Radler in Uniondale, NY. “Prosecutors are instructed to ask the hard questions that delve beneath the surface of a company’s compliance program to determine whether the program is truly effective and deserving of consideration in making charging decisions and formulating more lenient dispute resolutions,” Kaiser explains.

The guidance is clear that differences in risk profiles among

POLICY ACCOUNTS FOR ANTITRUST EFFORTS

The Antitrust Division of the DOJ has announced a significant policy change, saying it will now consider a corporation’s antitrust compliance efforts when deciding whether to file criminal antitrust charges.

This is an important change from previous policy, in which compliance efforts could be considered only at sentencing. An organization’s good faith efforts to comply with antitrust laws could not be considered when making charging decisions until now.

Assistant Attorney General Makan Delrahim announced the change at a speech at the New York University School of Law Program on Corporate Compliance and Enforcement on July 11. He said DOJ is acknowledging that a robust compliance program still may not prevent every instance of illegal behavior. The occurrence of misconduct “shows that a program was not foolproof, but that does not necessarily mean that it was worthless.”

Three questions will guide DOJ investigators in determining whether a compliance program was applied “earnestly and in good faith,” Delrahim said. First, did the compliance program address and prohibit criminal antitrust violations? Second, did the antitrust compliance program detect and facilitate prompt reporting of the violation? Third, to what extent was a company’s senior management involved in the violation?

Delrahim also identified these areas DOJ will consider in determining the effectiveness of a compliance program:

- Design and comprehensiveness of the program;
- Culture of compliance within the company;
- Resources dedicated to antitrust compliance;
- Antitrust risk assessment techniques;
- Compliance training and communication to employees;
- Monitoring and auditing techniques;
- Reporting mechanisms;
- Compliance incentives and discipline;
- Remediation methods. ■

SOURCE: Delrahim’s speech is accessible online at: <https://bit.ly/32IKpAc>.

companies require that DOJ make a “particularized evaluation” and “individualized determination” in assessing such compliance programs, Kaiser notes. However, receiving the benefit of prosecutorial discretion depends on an evaluation of three foundational compliance program areas: program design, program implementation, and program efficacy, he adds.

Key Questions to Consider

The updated DOJ guidance includes detailed questions relating to three broad program areas that healthcare organizations may use to evaluate the status of their own compliance programs and whether improvements are required to meet DOJ’s expectations. Kaiser provides this summary of the recurring themes reflected in these questions:

- Is compliance taken seriously by the organization as reflected in resource allocations, reporting lines, and the conduct of senior leadership?
- Is attention paid, through risk assessments and audits, to the riskiest aspects of the organization’s business operations? Are the criteria for those assessments and audits updated periodically to reflect the current risk environment?
- Are identified compliance issues addressed in good faith, or are they ignored?
- Do employees receive training appropriate to their positions and to the risk environment? Is training efficacy measured?
- Does the organization conduct appropriately scoped investigations in response to allegations of noncompliance? Are the results of those investigations shared appropriately within the organization?
- Does the organization demonstrate a commitment to

remediate misconduct by holding individuals accountable and correcting operational deficiencies that may have allowed the misconduct to occur?

- Are the organization’s policies and procedures effectively designed and communicated?
- Are there anonymous compliance reporting systems, are they used, and is information received through those systems appropriately handled and disseminated to those with responsibility to act on the information? ■

SOURCES

- **Geoffrey R. Kaiser**, JD, Partner, Rivkin Radler, Uniondale, NY. Phone: (516) 357-3161. Email: geoffrey.kaiser@rivkin.com.
- **Michael B. Lampert**, JD, Partner, Ropes & Gray, Boston. Phone: (617) 951-7095. Email: michael.lampert@ropesgray.com.

Specialty Pharmacy Can Improve Quality, Increase Revenue

Hospitals are finding that specialty outpatient pharmacies can improve quality of care and patient safety and bring in additional revenue. The process can require significant resources, but the benefits may include a greater return on value-based contracts.

A specialty pharmacy is a rare opportunity to improve quality of care while also increasing revenue for the hospital, says **Amy Andersen**, healthcare industry lead with North Highland Worldwide Consulting in San Francisco. She and her company have worked with Vanderbilt University Medical Center on various healthcare quality improvement

efforts. Recently, the university inquired about how to improve patient access to specialty drugs that typically are extremely expensive. For example, a 12-week course of therapy for the hepatitis C drug Harvoni carries a wholesale price of approximately \$95,000. Symdeko, used to treat cystic fibrosis, costs approximately \$290,000 annually.

Vanderbilt is eligible for the 340B federal drug pricing program, which means it could staff a specialty pharmacy for outpatients who need these high-cost drugs, Andersen explains.

“It was hundreds of millions of dollars in additional revenue that they were able to bring into the

organization. More importantly, it closed the care continuum by connecting the pharmacy to the clinics serving these patients,” Andersen reports.

“It created an ecosystem for supporting patients and allowed for the onsite medical education, consultation with both the pharmacist and clinician, and integration between all the clinicians and pharmacy staff. When patients go back to their homes, they are supported in adherence, which, of course, improves quality of care and outcomes.”

Vanderbilt also discovered that the integrated care model better allowed clinicians to understand and support

patients seeking preauthorization and trying to understand their copayments, Andersen says. Clinicians also gained a better understanding of social determinants of health.

“These eligible hospitals are serving populations that are quite vulnerable. They have a strong mission to serve their communities, which can be challenging in a financial sense,” Andersen says, noting that by providing a specialty pharmacy service, these revenue streams that otherwise would go to CVS and Walgreens are now coming into the hospital. “There are opportunities there when you engage the business side and clinical

side of the organization to look at the revenue coming in and decide how to use those resources to fulfill your mission.” However, implementing a specialty pharmacy can be challenging for any organization.

A large academic medical center like Vanderbilt has resources that smaller hospitals lack, including the existing pharmacy operation and infrastructure needed to support the new outpatient specialty pharmacy, Andersen notes.

“The biggest challenge for an organization setting up a specialty pharmacy is on the operations side. From a sustainability standpoint, they must have the resources and the market

with their patients to do more than break even and reap the rewards from a revenue standpoint but also from a patient safety and quality standpoint,” Andersen says. “They will want to assess to what extent they have risk contracts in which payments are based on patient satisfaction and outcomes measures. This can be a piece of the puzzle for organizations moving more into the value-based care model.” ■

SOURCE

- **Amy Andersen**, Healthcare Industry Lead, North Highland Worldwide Consulting, San Francisco. Phone: (415) 624-6572. Email: amy.andersen@northhighland.com.

Patient Watches Solve Safety Issue With Better Use of Resources

Hospitals often struggle with the need to provide close watch over a potentially dangerous patient without relying on skilled nurses or security officers who are needed elsewhere. Some hospitals are finding that a “patient watch” program is the right solution.

A patient watch is not the same as a sitter program in which a healthcare attendant is assigned to watch over a patient who is elderly, disabled, or otherwise impaired. The sitter is effective for patients who may be at risk of falling or other nonviolent risks, but they are not appropriate for patients who are potentially dangerous, explains **Ken Bukowski**, vice president of vertical markets for Allied Universal, a security and facility services company based in Conshohocken, PA.

Rather than a healthcare attendant, a patient watch involves a security officer posted with a patient for the purpose of protecting

that patient and others, Bukowski explains. For a patient watch to be appropriate, the patients must be identified according to state laws as a threat to themselves or others and placed in an involuntary patient status by the appropriate authority. Otherwise, directing a security officer to watch a patient could be construed as coercion or even false imprisonment, Bukowski cautions.

Some Require One-on-One Watch

Under some conditions, such as when a patient is suicidal, there must be a one-on-one patient watch with a qualified staff member monitoring the patient at all times, Bukowski explains.

In other situations, it is permissible to direct a staff member to watch more than one noncommitted patient as long as additional staff are

available to respond in an emergency, Bukowski says.

Those requirements can be difficult for some hospitals to meet. Most facilities do not have enough security officers to watch patients around the clock.

Pulling existing officers from their duties to do so would mean leaving other needs unfulfilled throughout the facility.

“We see a lot of hospitals pulling in CNAs and other clinical staff to do this just because they don’t have any other choice. The emergency department is already a busy environment, and no one wants to be taken away from their other duties to sit there and watch a patient,” Bukowski notes. “But these patients also can be disruptive, and these clinical staff are not qualified to handle a violent or dangerous patient. Even when you have clinical staff on this duty, you still end up having to call in a trained security professional.”

Using staff specially trained for patient watches is sort of a midpoint between the other options of instructing a clinical staff member or a hospital security officer to monitor the patient. Both those other staff members have skills that are needed elsewhere, and they are both more expensive to employ, Bukowski says.

“You’re taking nurses away from what they’re trained to do and what you’re really paying them for — taking care of patients in a medical situation. Or, you’re taking security officers away from their other duties and leaving other areas of the hospital unprotected while they watch this patient,” he explains. “A lot of hospitals call in their security officers for this, but when you pull that officer from duty in the hospital lobby, now your lobby is exposed and unprotected. Shuffling staff around doesn’t work because you had that security officer posted in the lobby for a reason. Now, you don’t have that coverage.”

Hospitals may have multiple patients requiring a watch at any one time, but the need fluctuates, Bukowski notes. A patient watch program can draw on either a security service or it can develop its own internal program of staff members specially trained for this task, he says. In either case, the hospital can schedule trained patient watch staff for high probability times like weekends. Other staff could be on call for times when such patients are less likely to appear.

“It’s important to look at the data and try to project when you will have these patients. It usually follows a pattern of weekends when you have people drinking too much and some evenings when people are more likely to come in with these kinds of problems,” Bukowski advises. “You can have staff there on those shifts,

ready to step in so that your more skilled staff don’t have to be pulled away. When a doctor orders a patient watch, it starts right then. If you don’t have the appropriate person to step in, you have to pull in someone who should be doing something else.”

Video Monitoring Possible

Another option is a watch program that uses video monitors. One staff member can watch monitors for several patients, but only if they are noncommitted, Bukowski says. If the patient is committed because he or she is at risk of suicide or other danger, a video monitor may be used if the staff member is constantly monitoring only that single patient, he explains.

“The person watching the camera has to do nothing but watch that monitor for that one patient. There must be a resource who can respond to the patient immediately. That can be either the person watching the monitor or another clinical or security

professional who can respond if something happens,” Bukowski says. “That’s a new directive from CMS.”

Bukowski notes that many hospitals are developing seclusion rooms that are grouped together, making it more feasible for a single patient watch staff member to monitor several noncommitted patients at the same time.

“The key to making a watch program work is to have people who are trained for this role. It’s not a matter of taking anyone who is willing to sit there and watch the patient,” Bukowski says. “They must be trained in recognizing signs of escalating behavior and respond to escalating behavior. Otherwise, you’re really not solving anything because you still have to pull in the medical staff if this person doesn’t know what to do and keep the incident from turning into a bad situation.” ■

SOURCE

- **Ken Bukowski**, Vice President, Vertical Markets, Allied Universal, Conshohocken, PA. Email: kenneth.bukowski@aus.com.

CE OBJECTIVES

After completing this activity, participants will be able to:

1. Identify a particular clinical, legal, or educational issue related to quality improvement and performance outcomes;
2. Describe how clinical, legal, or educational issues related to quality improvement and performance outcomes affect nurses, healthcare workers, hospitals, or the healthcare industry in general;
3. Cite solutions to the problems associated with quality improvement and performance outcomes based on guidelines from relevant authorities and/or independent recommendations from clinicians at individual institutions.

COMING IN FUTURE MONTHS

- Stroke care earns quality award
- More quick wins in quality improvement
- Tips for survey visits
- Moving from QI to CEO



CONSULTING EDITOR

Patrice L. Spath

MA, RHIT

Consultant, Health Care Quality
and Resource Management
Brown-Spath & Associates
Forest Grove, OR

NURSE PLANNER

Jill A. Winkler

BSN, RN, MA-ODL

Quality Improvement Advisor
Proprietor, True North Lean
Consulting Group, PLLC
Durham, NC

EDITORIAL ADVISORY BOARD

Kay Ball

RN, PhD, CNOR, FAAN

Professor of Nursing
Otterbein University
Westerville, OH

Claire M. Davis

RN, MHA, CPHQ, FNAHQ

Director of Quality
Middlesex Hospital
Middletown, CT

Susan Mellott

PhD, RN, CPHQ, FNAHQ

CEO/Healthcare Consultant
Mellott & Associates
Houston

CE INSTRUCTIONS

To earn credit for this activity, please follow these instructions:

1. Read and study the activity, using the provided references for further research.
2. Log on to **ReliasMedia.com** and click on My Account. First-time users must register on the site. Tests are taken after each issue.
3. Pass the online test with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the test, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be emailed to you.

CE QUESTIONS

- 1. What is a nudge unit?**
 - a. A behavioral design team comprised of people with skills in behavioral economics, psychology, and related fields.
 - b. A quality assessment team comprised of people with skills in employee education and data consolidation.
 - c. A compliance team that works to improve an organization's compliance with standards and regulations through small improvements.
 - d. An executive team that works to deliver the organization's goals and message to frontline staff.
- 2. In the Penn State Nudge Unit, who is on the steering committee?**
 - a. C-suite executives
 - b. Leadership from IT, clinical care, and behavioral economics
 - c. Patient advocates and community representatives
 - d. Academic leaders from institutions across the country
- 3. In the most recent survey by The Leapfrog Group, what percentage of the reporting hospitals failed to meet Leapfrog's expanded standard for never events?**
 - a. 10.4%
 - b. 25.4%
 - c. 46.4%
 - d. 68.4%
- 4. What is one takeaway from the new guidance from the Criminal Division of the Department of Justice (DOJ) regarding compliance programs?**
 - a. DOJ will consider the existence of a compliance program as a given and look more deeply at how it is structured and used.
 - b. DOJ will give no weight to the existence of a compliance program if laws are violated.
 - c. DOJ will automatically reduce civil and criminal penalties if a compliance program is in place.
 - d. DOJ will look only at the results of a compliance program, not how it is structured.