Survey readiness

Focus for 2017 will be on new survey process, infection control and documents

Expect The Joint Commission to continue to crack down on hospitals that do not closely adhere to evidence-based guidelines, prepare for more changes as TJC tweaks its new survey process and plan now to possibly greet surveyors earlier than you might have thought.

Even more new requirements can be expected later this year or early next year.

By now, most if not all of the major changes announced by TJC and CMS in 2016 are being implemented, from the commission’s new scoring matrix and overhauled survey process to CMS’ (see Survey, p. 6)

Patient safety

Establish responsibility, educate staff for best recall notice management

Assign responsibility for recalls across a multi-disciplinary team but also identify who overall is responsible for ensuring a proper response as your first steps in designing or reviewing your recall management plan.

Depending on the nature of the problem, failing to comply with recall notices can result in unnecessary patient safety risks and expense to the hospital, as well as an overall greater chance (see Recall, p. 7)

TJC’s Executive Briefings: How hospitals can succeed in 2017

Want to maintain your accreditation? Find out what The Joint Commission is targeting in 2017 by joining former TJC executive Jennifer Cowel for this on-demand webinar as she reviews new and changing requirements covered at the recent Executive Briefings. Get more info at decisionhealth.com/conferences/A2698.
Survey readiness

2017: Infection control, properly kept medical records top clinical watchlist

Whether they concern surgical attire, medical devices or the use of catheters, review the latest evidence-based guidelines on infection control, incorporate them into your policies and educate staff because The Joint Commission (TJC) will be watching.

TJC surveyors will be looking for how you will be implementing new standards on antimicrobial stewardship, updated National Patient Safety Goals on catheter-associated urinary tract infections (CAUTIs) and protocols in surgical areas including air-pressure relationships, surgical attire and cleaning of medical devices.

Here are some highlights of what surveyors will look for in 2017:

- **New IC-related standards effective Jan. 1:** TJC implemented new antimicrobial stewardship standards and updated its National Patient Safety Goal on CAUTIs as it ramps up overall concerns over hospital infection control. Hospitals should be ready to present policies and show that staff have been educated in the new or updated programs (UC 10/3/16).

However, the changes are not huge, says Kurt Patton, a former Joint Commission director of accreditation services and founder of Patton Healthcare Consulting, which serves as technical adviser to Inside the Joint Commission. Patton noted that he’s seen only one hospital in the past year that “was not already geared up for antimicrobial stewardship.”

Having said that, concerns over antibiotic- and antimicrobial-resistance continues to grow, with guidelines and warnings last year from the CDC and World Health Organization, and perhaps most notably with funding from Congress for programs to target overuse of antibiotics.

- **Surgical attire:** Compliance officers were reporting last year that surveyors were scoring hospitals if members of surgical teams did not have the proper gowns, head covers or other protective wear to restrain hair and beards.

The RFIs came in the wake of best practices issued by the Association of periOperative Registered Nurses on proper surgical attire (UC 10/8/16).

Calling it a “hot-button topic,” Patton warns that the controversy is not over. “It is believed that CDC will soon issue a guideline on this.” Watch for arguments or issues to be taken with “hair covers, dangling masks, wearing scrubs out of the OR, contaminated shoes, short sleeve scrubs, wearing the same head cover between cases, what may be different and acceptable for anesthesia staff versus surgical team,” and more, predicts Patton.

- **Overall infection control:** While the recurring theme for the last few years has been proper cleaning of endoscopes and duodenoscopes, concerns are expanding to the proper maintenance and disinfection of other medical devices and even proper cleaning of surgical teams did not have the proper gowns, head covers or other protective wear to restrain hair and beards.
environmental areas, according to the annual top 10 technology hazards list put out by the Pennsylvania-based patient safety organization, ECRI Institute (IJC 11/28/16).

Start adhering “in detail” to the Association for the Advancement of Medical Instrumentation (AAMI) guidelines, advises Jennifer Cowel, a former TJC executive and now president of Patton Healthcare Consulting.

At Executive Briefings and other settings, TJC officials have said that hospitals must not only base IC policies on evidence-based guidelines, but they must follow those policies and surveyors will ask staff to go into detail about IC processes. Failures will not only result in RFIs, but quite possibly a call of a threat to life and possible revocation of Medicare funding.

Among other things surveyors will be watching for, warns Cowel, are whether dirty items are being stored without a bio-hazard label and how and even if pre-cleaning of medical devices is being done at the point of use.

Surveyors are now also starting their work by checking that the proper positive-negative air pressure relationships are maintained in surgical areas. Hospitals have been told they might be able to avoid major accreditation troubles if they can pinpoint the problem, correct it and show that the fix has remained steady over time (IJC 10/31/16).

In addition, expect questions on how your hospital handles its recall notices, especially related to IC and medical devices. TJC’s infection control specialist Lisa Waldoski called out hospitals during Executive Briefings in September for not managing recall notices effectively and leaving patients open to risk. (For tips on recall notice management, see article p. 1)

- **Medical records must be maintained.**
  While hospitals have been doing much better getting physicians and other clinicians to time, date and sign orders and record updates, surveyors are also cracking down on other concerns. Among them are:
  - **Hospitals must have protocols in the medical record,** warns Cowel. “For example, if I am treating someone based on the hospital’s hypoglycemic protocol, the protocol must be in the actual medical record — not in a binder somewhere.”
  - **TJC is now scoring the new diagnostic imaging standards** that were published a year ago, especially as they relate to medical records. “Specifically, we are seeing hospitals scored if they do not have written and approved protocols for CT with contrast or MRI with contrast,” says Cowel. “These need to be written and they need to be reevaluated on some periodic basis. Put these on a schedule for review to prevent these falling through the cracks.”
  - **No texting of orders.** After initially approving the ability of clinicians to use secure text messaging to give orders early last year, TJC put that on hold in June, apparently after objections from CMS (IJC 6/13/16). Now in TJC’s December issue of Perspectives newsletter, the commission has said secure text messages are “not acceptable.” TJC has outlined recommendations it says it came up with in concert with CMS on policies hospitals should have to ban texting of orders and when verbal orders are acceptable when a clinician cannot use computerized provider order entry (CPOE) to update the medical record (see link below). — A.J. Plunkett (aplunkett@decisionhealth.com)

**Resources:**
- Joint Commission on texting of orders: www.jointcommission.org/assets/1/6/Clarification_Use_of_Secure_Text_Messaging.pdf
- Joint Commission report on revised NPSGs on CAUTIs: www.jointcommission.org/assets/1/18/R3_Report_Issue_9_CAUTI.pdf

**Survey readiness**

**New processes, new standards: Here’s what survey will look like in 2017**

Now is the time to get policies updated with new or revised standards, ensure documents are at the ready to back up clinical policies and prepare staff to talk about various protocols, especially involving the cleaning of medical devices.

That includes getting senior leadership up to speed on all the changes and ensuring they know they might be quizzed by surveyors as well.

If you are expecting a survey in 2017, here is what to remember:

- **Surveyors may be showing up earlier or later.** But you can imagine which is more likely as TJC changes up the timetables for when surveyors arrive for a hospital’s unannounced triennial accreditation visit.
TJC is committed to more random survey visits, apparently to address concerns from CMS, warns Kurt Patton, a former Joint Commission director of accreditation services and founder of Patton Healthcare Consulting, which serves as technical adviser to Inside the Joint Commission.

CMS has become worried about how often TJC has been showing up for a hospital’s survey three years to the month — sometimes to the week — of the commission’s last visit. “My understanding is that CMS felt it was too consistent, thus the required randomization in 2017,” Patton notes.

- Prepare for concerns about the new scoring matrix. As of Jan. 1, TJC accreditation reports will use the new Survey Analysis for Evaluating Risk (SAFER) matrix for scoring RFIs. When doing rounds or mock survey exercises, start using the nine-box, color-coded matrix to get staff familiar with the process, experts have said. Include leadership in the education process.

  “On the SAFER matrix, the most likely issue is going to be consistency versus subjectivity,” says Patton.

  Surveyors will go over the new processes involving the matrix and changes to the clarification process during the opening and exit conferences, according to the just published 2017 Survey Activity Guide.

  But expect some consternation as hospitals, surveyors and leadership all get used to the new scoring (IJC 8/8/16).

  “Since the higher risk items will require senior management involvement, senior management is not going to be pleased if too many items turn up red or orange,” observes Patton.

  And the subjectivity of the new matrix will have an impact.

  “Having been on a five-person mock survey recently where we tried to use this same logic, we realized there are differences of opinion between team members,” Patton says.

- Remember: No documents, no clarification.

  Once a surveyor does ask for a document or policy, be prepared to provide it quickly or face an RFI. As of Jan. 1, documents “not available at the time of survey will no longer be eligible for the clarification process,” says Mark Pelletier, TJC’s chief operating officer for accreditation and certification operations (IJC 12/12/16).

  While surveyors in other areas may allow a “reasonable” amount of time for documents to be found, that will not be the case with LS and EC documents, TJC has warned. Citing an NFPA requirement that records of inspections, tests and maintenance of fire protection systems and its components “shall be made available to the authority having jurisdiction upon request,” TJC Engineering Director George Mills has said LS and EC documentation must be produced on demand or the hospital will be cited with an RFI.

- Interim Life Safety Measures (ILSM) must become a daily exercise. Review your ILSM policy and procedures with facilities staff because a surveyor will ask you to mitigate Life Safety problems as soon as an RFI is identified. Compliance managers must be able to cite one of the measures identified in your policy. That ILSM will be noted in the RFI language, which becomes part of the survey report, according to TJC (IJC 12/12/16).

- LS RFIs must be fixed within 60-day window.

  The elimination of the Statement of Conditions and Plan for Improvement process to self-identify deficiencies also did away with the automatic extension to repairs or renovations outlined in a facility’s 45-day PFI list. While facilities can apply to CMS, via TJC, for a time-limited waiver (TLW), there is no guarantee that the waiver will be approved, say TJC officials. There is not even a guarantee the waiver decision will come out before the end of the now-standardized 60-day, evidence-of-standard-compliance (ESC) window that every hospital must meet to remedy RFI. Mills has advised hospitals to have funds ready for quick fixes (IJC 9/19/16).

- Surveyors will be asking about newly updated standards.

  The new antimicrobial stewardship standard was effective as of Jan. 1, so expect surveyors to be asking about stewardship efforts as it examines competencies, medical staff credentialing and privileging, reviews medication management and conducts patient tracers. Document lists and other materials related to the stewardship effort have been updated in the new Survey Activity Guide for 2017 (see link in Resources).

  Of course, as of Jan. 9, TJC surveyors will be using new and revised EPs in the LS and EC standards chapters approved to align with CMS’ adoption of the 2012 editions of the LSC and NFPA 99 Health Care Facilities Code.

- TJC expects information technology (IT) staff involved in emergency management. One of the changes to hospital surveys in 2017 is the addition of an IT representative among the suggested participants in the Emergency Management discussion with TJC surveyors, according to the 2017 SAG. This, along with the CMS’ adoption Sept. 16 of emergency preparedness Conditions...
of Participation (COPs), is a clear signal that EM is taking on a higher priority with surveyors. While the new COPs are not effective until November 2017, hospitals should begin reviewing policies and plans now to ensure they meet all the requirements, says Patton and others. TJC and CMS have both said, however, that hospitals that meet Joint Commission requirements already are in compliance with a majority of the new COPs.

- **Post survey help available.** While there might be more questions now about the use of the SAFER matrix, there will be more help understanding it as well. TJC has promised that, beginning with surveys in January, it will also make a matrix tool and user guide available online to help hospitals and other organizations understand their just completed accreditation report.

  The tool will be available through the organization’s Joint Commission Connect site, according to information released by TJC. — A.J. Plunkett (aplunkett@decisionhealth.com)

**Resources:**

- Revised Joint Commission LS and EC standards: [https://www.jointcommission.org/standards_information/prepublication_standards.aspx](https://www.jointcommission.org/standards_information/prepublication_standards.aspx)
- TJC’s Survey Activity Guide: [https://www.jointcommission.org/2017_survey_activity_guide](https://www.jointcommission.org/2017_survey_activity_guide)

**Information management**

**Call it telecommuting or working remotely, it needs a HIPAA policy**

Review your policies for protecting patient data when administrative or medical staff work off site. Doing so could not only help save your hospital from costly fines, but a potential RFI as well.

The HHS Office for Civil Rights (OCR) appears particularly concerned now about safeguarding the information in the hands of telecommuters.

Two of the most notable OCR enforcement actions taken in the past year involved telework glitches that led to the compromise of patient protected health information (PHI). In 2016, an administrative law judge upheld a $239,800 civil monetary penalty against infusion, respiratory care and medical equipment provider Lincare for an incident involving an employee who left PHI in a car that was in the possession of her recently estranged husband. This resulted in the impermissible disclosure of the PHI. He filed a complaint with OCR.

While the judge noted that PHI needed to be removed from Lincare’s offices on occasion, Lincare didn’t include in its policies how to safeguard the information when it was offsite.

Indianapolis-based radiation oncology practice Cancer Care Group agreed to pay $750,000 after it ran into a similar problem. Unencrypted backup tapes containing the PHI of more than 50,000 patients were stolen from a telecommuting employee. OCR found a number of problems, including the medical group’s lack of a policy regarding how PHI should be removed from the premises and protected.

**Telework prone to HIPAA risks**

It is increasingly common for employers, including health care providers, to allow staff to work off site on a full- or part-time basis. While it’s most commonly seen as working from home, off site means anywhere but the office, including on a train, in a coffee shop, while traveling from patient to patient or elsewhere, points out attorney Michael Kline with Fox Rothschild in Princeton, N.J.

But taking work off site increases the risk of HIPAA violations because the provider is no longer in control of some of the technical and physical safeguards required by HIPAA’s security rule to protect the PHI, points out attorney Elizabeth Litten, also with Fox Rothschild.

“There are more opportunities for things to go wrong,” Litten warns.

The increased use of telework, coupled with OCR’s new focus on smaller breaches, also will likely increase the number of incidents involving PHI off premises.

“There’s a heightened level of security and [IT] sophistication with telecommuting because there’s a heightened risk,” says Kline.

**What does TJC say?**

Everyone in health care is concerned about keeping up with documentation these days. But taking work off site, even with the good intention of maintaining records, can pose accreditation problems on top of OCR scrutiny.

While The Joint Commission (TJC) does not specifically enforce HIPAA regulations, it does require under Information Management standards that hospitals must
How to handle 8 telework issues

Take these steps before you allow staff to take PHI home:

1. **Have clear policies about what practices are accepted and how workers will protect the data.** There is no one best practice, but consider requiring encryption and barring telework from public places. If the PHI is on a laptop, you can limit the laptop’s use to business purposes only. The failure to delineate how to protect PHI in particular is what tripped up Lincare and Cancer Care Group.

2. **Determine what hardware and software will be allowed and how it must be configured.** For instance, you may want to restrict telework to facility-owned laptops. You’ll need firewalls, antivirus software and up-to-date security patches, and you could require the use of a secure network, such as Citrix, to access office computers, says Litten.

3. **Make sure that the PHI can be password-protected, encrypted or otherwise segregated** if the employee doesn’t have a dedicated computer. Then family members who have access to the computer can’t view the PHI. “You don’t want it accessed by little children who want to look at Bubble Guppies,” says Kline.

4. **Double check that your insurance policies allow telecommuting** and the removal of PHI from the premises. If so, make sure you’re aware of any limitations or special requirements, says Kline.

5. **Include PHI off the premises as part of your facility’s overall risk assessments and management.** Simply because it’s off site does not mean that it’s not part of your overall HIPAA compliance program.

6. **Incorporate protection of PHI into your facility’s telecommuting policy.** Be clear regarding who is and is not entitled to telework. Employees who aren’t authorized need to understand that they can’t take work home to, say, catch up on documentation. Staff engaged in telework must be trained in and understand the policies. Also make it clear that violation of these policies will subject an employee to disciplinary action.

7. **Get the promise to protect PHI in writing.** As with telework in general, some compliance is based on good faith on the part of the employee, but it should be part of the employee handbook. Telecommuting employees should provide some sort of assurance, such as a signed a statement agreeing to abide by the facility’s policies and procedures.

8. **Monitor how telecommuters handle PHI.** If telecommuters can access their employer’s network computers, IT personnel should be able to monitor and follow audit trails. “What kind of oversight do you have?” says Kline. — Marla Durben Hirsch (jcEditors@decisionhealth.com)

**Resources**

- Cancer Care Group Resolution Agreement: [www.hhs.gov/sites/default/files/cancercare-racap.pdf](http://www.hhs.gov/sites/default/files/cancercare-racap.pdf)

**Survey**

(continued from p. 1)

adoption of updated NFPA fire safety codes and the subsequent changes to Life Safety and Environment of Care standards.

But expect TJC to continue to fine tune many of those changes as full implementation begins to reveal flaws and the need for improvement to its own processes, experts say.

“The new clarification process will be important to watch, to see what kind of push back occurs from hospitals,” observes Kurt Patton, a former Joint Commission director of accreditation services and founder of Patton Healthcare Consulting (PHC). The Naperville, Ill., firm serves as technical adviser to Inside the Joint Commission.

TJC says it wants to cut down on clarifications after the survey visit by encouraging more discussion of RFIs on site and not allowing hospitals to produce documents after the fact to show evidence of survey compliance, among other changes (IJC 12/12/16).
In practice, the changes may be more difficult than TJC hopes. “I will be surprised if clarifications do not return,” notes Patton.

TJC does promise that during the opening and exit conferences for surveys in 2017, surveyors will go over the new processes involving clarifications as well as the use of the newly minted Survey Analysis for Evaluating Risk (SAFER) matrix, according to TJC’s just-published 2017 Survey Activity Guide. *(For a watchlist of clinical concerns in 2017, see p. 2; for a review of what surveys will look like in 2017, including more random survey visits, see p. 3.)* — A.J. Plunkett (aplunkett@decisionhealth.com)

Resources:

- TJC’s Survey Activity Guide: [https://www.jointcommission.org/2017_survey_activity_guide](https://www.jointcommission.org/2017_survey_activity_guide)

Recall

*(continued from p. 1)*

of using equipment and supplies that are not always functioning to their expected level.

“It’s important to know where the products live in the organization and who’s responsible,” says Kate Jester-Brod, vice president of customer success at EOScene Corp., a Seattle-based health care facility management software company. “Sometimes that’s one person, sometimes it’s an entire zone. Both ways work; it’s just important that responsibility is established.”

Patient safety is on the line

The management of recalls takes on greater importance as hospitals continue to struggle with infection control related to hard-to-clean medical devices, says Lisa Waldowski, IC specialist with The Joint Commission (TJC).

Waldowski noted during TJC’s Executive Briefings in September, that the FDA, CDC and other agencies have issued hundreds of recalls and notices associated with duodenoscopes, automated endoscope reprocessors and related cleaning products and equipment in recent years.

Hospitals must do a better job of managing recalls and other safety notices to protect patients as well as avoid possible TJC calls of threats to life — which could threaten a hospital’s accreditation if IC warnings go unheeded because they got lost in the system, Waldowski warned.

When managing recalls, there should be three key components to your response plan, Jester-Brod recommends:

- Receive and disseminate the recall information;
- Determine who needs to be informed when a given recall occurs; and
- Formulate a checklist for what happens next.

The actual recall process varies based on the item being recalled and the type of facility or procedure affected, but in general patient notification and regulatory reporting are part of the process, along with directly resolving the issue.

Tap different staff members to handle different sorts of recalls — an environment of care leader to handle equipment recalls, an information technology staff member to handle software recalls, or a pharmacist or other clinician...
to handle drug and medical recalls. Experts also have said that a good recall process includes identifying more than one person to receive the notices to ensure recalls are not missed if someone is out of the office (ECL 4/29/13).

Remember that software recalls can be serious and vast. Data released earlier this year by health waste management company Stericycle showed that 280 software-related health care equipment recalls have occurred since 2012, affecting approximately 783,000 total units.

**Keep staff informed of process**

Whatever a given recall process might be, informing staff is key.

“The backbone of monitoring recalls is that the staff knows the process,” says Jester-Brod. “You could add staff knowledge questions to grand rounds. Ask people, 'Hey, what happens in the case of a recall in your department?'”

With so many pieces of equipment in the average hospital — and so many recalls — it can be difficult to keep track of them all. As such, emphasize the most critical equipment first.

“The sheer volume of equipment is daunting. There are potentially tens of thousands of pieces to track,” notes Mairead Smith, project officer in the health devices group of the ECRI Institute, a Pennsylvania-based nonprofit specializing in research around procedures, devices and drugs. “Prioritize what devices most need to be kept up to date, like life support, network and other things [whose failure] might cause a high risk of patient harm.”

Recalls also can be prioritized internally and response plans tailored accordingly based on the immediate threat level or importance to operations.

“Know what’s important and what’s not,” says Jester-Brod. “How do you prioritize an equipment recall versus a vaccine recall? What’s more important? There is definitely a lot of white noise in a hospital. As a charge nurse, or whoever the person might be, you learn to pay attention to a given set of communications because that’s your job.”

**Make recalls easier with software**

Don’t wait until a recall occurs to check in on your equipment. In the case of connected devices, IT or engineering staff should work to keep software up to date, as this makes any recall process easier — not to mention enhances overall performance — and can correct glitches before a recall is necessary. Monitor which version of the software is being used.

“It’s important to have information about the version of the software in order to facilitate recall management,” explains Erin Sparnon, health devices manager also in the ECRI Institute’s Health Devices Group. “You need to track the software version because it facilitates other processes.”

Use the annual inspections for preventive maintenance as a time to make sure key devices are current on their software versions and are not subject to recall.

Several tools can help provide recall information. The FDA’s MedWatch service, for example, is a free source of recall information. The ECRI Institute has Alerts Tracker, a Web-based tool that distributes information, including recall information, about medical devices, blood products, food products and pharmaceuticals to the appropriate staff.

Before any vendor agreement or software purchase, do homework on the business to see whether it’s a proper fit.

“Going toward a vendor, the first thing is to understand the landscape,” says Jester-Brod. “Where or who have they worked with? Research facilities treat recalls with higher intensity than a family doctor’s office. Are they health care or just IT folks or both?” — Scott Harris (ijc_editors@decisionhealth.com)

**Resources:**

- ECRI Institute Alerts Tracker: [https://www.ecri.org/components/AlertsTracker/Pages/default.aspx](https://www.ecri.org/components/AlertsTracker/Pages/default.aspx)

**FDA**

**Effective now: Powdered gloves out**

Citing a risk of allergy or infection, the Food and Drug Administration in December banned the use of powdered gloves during surgery or when examining patients at any time.

In a final rule published Dec. 19, the FDA bans the gloves as well as the absorbable powder used in surgical gloves “because these products present unreasonable and substantial risk to health care providers, patients and other individuals.”

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