

# The **Hospital Conditions** of Participation and Interpretive Guidelines

2020 Edition

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Available as a download:

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# Introduction

Every hospital should have a copy of up-to-date Centers for Medicare & Medicaid Services' (CMS) *Conditions of Participation (CoP)* and *Interpretive Guidelines* (IG) because surveyors use them to guide inspections, and following such guidelines helps to ensure full reimbursement. This document is also referred to as the *State Operations Manual*.

This book reproduces the most current version of the CMS hospital *CoPs* and IGs verbatim. It includes CMS' survey protocol guidelines, which includes a list of questions surveyors will ask and the policies they will look for during an on-site visit.

This book also reproduces the Emergency Medical Treatment and Labor Act (EMTALA) regulations, also reprinted verbatim. Medicare participating hospitals must meet these regulations, which require hospitals (including critical access hospitals) with emergency departments to provide a medical screening examination to any individual who comes to the emergency department and requests such an examination.

Our goal is to make it easier for you to understand the *CoP* requirements and have a successfully survey and receive full reimbursement. We hope you will find this book to be an essential resource to help you comply with CMS regulations.

## What to Look For in 2019: Ligature Risk, Infection Control, Drug Safety, and More CMS Pressure on AOs

Make sure your staff knows and implements your policy on continuous observation of suicidal patients, check and recheck that air pressures are appropriate to the room, update infection control procedures to the latest recommendations, and be prepared for surprise surveys.

Hospitals are reporting that surveyors from The Joint Commission (TJC) and other accrediting organizations (AO) are showing up days to months early, a likely response to increasing pressure from CMS to get stricter on patient safety.

In turn, the increasing pressure from CMS is a response to media criticism and a Senate subcommittee investigation into whether AOs are doing their jobs well enough. And in the latest indication of increased scrutiny, CMS in December asked for public comment on whether AOs have sufficient barricades to conflicts of interest created by related consulting services, a direct result of the Senate investigation.

#### NPSG changes, EPA rule

In 2019, hospitals face new compliance challenges from updated TJC National Patient Safety Goals in the management of medications for anticoagulant therapies as well as in protecting patients at-risk for suicide or other self-harm. Both are effective July 1.

In addition, the EPA released its long-awaited final rule on the management of hazardous waste pharmaceuticals, which will put an even stronger spotlight on your pharmacy and medication management as surveyors continue to look at sterile compounding requirements under the U.S. Pharmacopeia's USP < 797 > standards already in effect.

That's on top of increased emphasis on protecting your staff through the proper use of personal protective equipment and strong training in safety procedures related to infection control in dialysis services and the scheduled implementation of USP < 800 > standards for the handling of drugs that can be hazardous to nurses, clinicians and other staff in the course of their jobs.

Don't forget all the other hot topics that have dominated surveys in the last two years, including complying with the new fire safety requirements under NFPA 101 *Life Safety Code*\*, infection control of medical equipment and devices, the reduction of healthcare-acquired infections (HAI) and ligature risk assessments as required by CMS following a major TJC patient safety initiative launched more than a year ago.

Unmitigated ligature risks and staff failures to maintain continuous 1-to-1 observation of at-risk patients, especially in violation of a hospital's own policy, were frequent problems cited by CMS state regional surveyors, according to the federal agency on its new "Quality, Certification and Oversight Reports" website that highlights hospitals with "recent substantial deficient" practices.

#### Some topics remain hot

"As to the hot topics, ligature risks remain at the top of the class," says **Steven A. MacArthur,** senior consultant with The Greeley Company in Danvers, Massachusetts. "Other accreditation organizations, as well as CMS are starting to focus on this, so it's gone way beyond a TJC construct."

Other topics remain hot, he says. "There's still a fair amount of ongoing [survey focus] relative to the management of the surgical environment (temperature, humidity, air pressure relationships, etc.), as well as the million little things that can go squirrelly over the course of a multi-day survey process," warns MacArthur.

"That said, I think the overall 'push'—beyond ligature risks—is going to continue to be to those instances in which the physical environment and infection control intersect," says MacArthur. "The truth of the matter is that the number of folks harmed in fires in hospitals is miniscule in comparison to folks harmed from HAIs, so I think the AOs are going to have to keep their focus on areas like surgery (and other procedural areas), central processing, etc."

Still, keep staff on their toes, especially in training to prevent fires in the oxygen-rich environment of a surgical suite.

"I do think a lot of folks are going to get 'dinged' if they do not have surgical fire safety timeouts in their preoperative processes—this was prominently mentioned during the September [TJC] Executive Briefings and I am anticipating a lot of queries during survey," warns MacArthur.

Originally published in the February 2019 edition of Briefings on Accreditation & Quality.

#### **Dialysis Tips**

Expect more focus on hemodialysis this year. The Joint Commission (TJC) and CMS have indicated that surveyors will focus on infection control practices, including isolation of infectious patients and medication storage, preparation, and administration.

Here are some additional tips from **Kathleen Good, MSN, RN,** a former surveyor with TJC and now an associate of Patton Healthcare Consulting, for ensuring you keep patients safe and meet surveyor expectations. Among other areas, Good has expertise in end-stage renal disease and dialysis programs.

#### Use personal protective equipment

In addition to gloves, staff overseeing dialysis of patients should wear gowns and face protection to protect themselves as needed:

- During initiation and termination of dialysis
- When cleaning dialyzers
- When handling lab samples

All of these procedures are at high risk for splash of contaminated fluids. Personal protective equipment should be changed if it becomes dirty.

#### Separate clean from contaminated areas

Often hospitals have a single space for dialysis operations. However, there must be distinct clean and contaminated areas, says Good.

Clean areas should be used for the preparation, handling, and storage of medications and unused supplies and equipment. Contaminated areas are where used supplies and equipment are handled.

Do not handle or store medications or clean supplies in the same area as where used equipment or blood samples are handled. And remember: Treatment stations are contaminated areas, warns Good.

#### **Dedicate supplies to a single patient**

Remember that any item taken to a patient's dialysis station could become contaminated.

Items taken into the dialysis station should either be disposed of or cleaned and disinfected before being taken to a common clean area or being used on another patient. Do not return unused medications or supplies taken to the patient's station to a common clean area (e.g., medication vials, syringes, alcohol swabs).

Here are guidelines for carrying medications:

• Do not use the same medication cart to deliver medications to multiple patients

- Do not carry medication vials, syringes, alcohol swabs, or supplies in pockets
- Prepare the medication in a clean area away from the patient station and bring it to the patient station for that patient only at the time of use

#### Cleaning, disinfecting the station

Train staff to take particular care when cleaning and disinfecting stations between patients, warns Good. Personnel must be able to talk about the process with surveyors.

Cleaning should be done using cleaning detergent, water, and friction, and it is intended to remove blood, body fluids, and other contaminants from objects and surfaces, notes Good.

Meanwhile, disinfection is a process that kills "many or all remaining infection-causing germs on clean objects and surfaces."

Remember to use an EPA-registered hospital disinfectant and follow the label's instructions for proper dilution. Also, wear gloves during the cleaning/disinfection process.

Originally published in the April 2019 issue of Briefings on Accreditation & Quality.

## Joint Commission and CIHQ Respond to CMS Conflict-of-Interest Concerns

#### CMS openly ponders legality of AOs' consulting businesses

A query by CMS officials questioning whether accrediting organizations (AO) that also offer consulting services face a conflict of interest drew an array of responses, including a vigorous defense by The Joint Commission (TJC).

TJC and the Center for Improvement in Healthcare Quality (CIHQ) were among the first hospital AOs to have responses posted online as part of the public request for information posted in the *Federal Register* in mid-December.

CMS asked the public to weigh in on whether AOs that also offer consulting services have or create a public perception of conflict of interest. The request was made ahead of potential new regulations, according to CMS.

There were at least 100 comments from people or organizations responding to the request. Many of the comments said that TJC and other AOs keep sufficient firewalls to avoid conflicts of interest and expressed concern that more regulation would make hospitals and other healthcare facilities less safe.

"Why do you continue to make things more difficult for facilities to meet compliance standards? This would have a negative impact on facilities to maintain regulation. Facilities are having a difficult time to maintain compliance with the ever decreasing amount the health care facilities are reimbursed for services," said one member of the public.

However, another public commenter said that she was against the practice of AOs "providing consulting as I have personally seen questionable interactions, both overt and implied." That included one hospital system that was encouraged to use a product from an AO affiliate to improve survey scores, and the cross-marketing of services across the AO platforms.

TJC provided a 14-page response to CMS' request for information, noting that TJC and its affiliates, Joint Commission Resources (JCR) and the Joint Commission Center for Transforming Healthcare, are all non-profit companies with separate organizations and boards of directors. The response was introduced by a letter from **Margaret VanAmringe**, **MHS**, executive vice president of public policy and government relations.

TJC's response provided a history of its efforts to avoid conflicts of interest, outlining the creation of an organizational and cultural firewall decades ago that prohibits and prevents consultants from JCR and surveyors from TJC communicating about clients.

"The structures and processes implemented and monitored by The Joint Commission and JCR to prevent any sharing of confidential consulting information with Joint Commission accreditation personnel are

necessary for preventing any real or perceived conflict with the provision of consulting services. Firewall Policies and Procedures have been tested by independent, external auditors and by the Government Accountability Office (GAO)," wrote TJC in its comment.

While the firewall policy has evolved along with TJC and JCR over the years, the commission's response noted that "what has never changed is the core principle addressed by the policy—to protect the integrity of The Joint Commission accreditation process. The policy was tested by GAO investigators in 2006, with a final report issued December 2006 that concluded:

Despite The Joint Commission's control over JCR, the two organizations have taken steps designed to protect facility-specific information. In 1987, the organizations created a Firewall—policies designed to establish a barrier between the organizations to prevent improper sharing of this information. For example, the Firewall is intended to prevent JCR from sharing the names of hospital clients with The Joint Commission. Beginning in 2003, both organizations began taking steps intended to strengthen this Firewall, such as enhancing monitoring of compliance.

Ensuring the independence of The Joint Commission's accreditation process is vitally important. To prevent the improper sharing of facility-specific information, it would be prudent for The Joint Commission and JCR to continue to assess the Firewall and other related mechanisms.

TJC also offered a point-by-point rebuttal to specific concerns CMS outlined in its request for information.

CIHQ, meanwhile, kept its comments to just over one page, in a letter written by **Richard Curtis**, CEO of the Texas-based AO. CIHQ was formally approved as an AO in 2013 following the extended CMS application process.

Like TJC, Curtis noted that CMS already requires AOs to demonstrate sufficient protections against conflicts of interest as part of that initial application and any renewal applications. "CIHQ respectfully questions why additional rules would be required," wrote Curtis.

And like other commenters, Curtis said more regulations could hurt healthcare organizations trying to comply with standards and improve patient safety.

"Some AOs—including CIHQ—offer a variety of support services to their accredited providers to help them understand standards and regulations, and provide tools to help them develop compliant processes. These take the form of standards interpretation, education programs, template policies, and documentation tools. These services do not assess a provider's compliance, but rather provide information to the provider to help them comply. We are concerned that an overly expansive definition of what constitutes consulting would rob providers of vital sources of assistance that do not pose a conflict of interest."

Originally published in the April 2019 issue of **Briefings on Accreditation & Quality.** 

## Ebola, Zika, and the Flu: CMS and CDC Want Action on Emerging Infections

Between antibiotics losing their effectiveness, people refusing to vaccinate, and constant lapses in infection control, the threat of disease should be on the top of every physician's and nurse's mind. And not just because CMS and the CDC are taking notice—although they are.

The CDC issued a bulletin urging hospitals and other healthcare facilities to remain prepared for infectious disease outbreaks.

"The ongoing outbreak of Ebola virus disease (EVD) in the Democratic Republic of Congo (DRC) serves as a reminder for U.S. healthcare facilities to review their infection prevention and control processes to safely identify and manage patients with communicable infections," states the CDC.

Meanwhile, CMS has issued a new memo highlighting concerns over potential outbreaks of infections like Ebola, the Zika virus, or influenza.

#### **CDC** recommends action

The CDC's Clinician Outreach and Communication Activity bulletin comes on the heels of a CMS revision to interpretive guidelines for surveyors implementing the 2017 *Conditions of Participation (CoP)* on emergency preparedness.

The revision, among other things, emphasizes that healthcare organizations must consider emerging infectious diseases (EID) such as Ebola and influenza when assessing all possible hazards for which the facility must prepare.

Include EID threats as a separate line item for your hazard vulnerability assessment (HVA), which is required by both CMS and The Joint Commission, recommends **Steven MacArthur**, a former hospital safety officer and now a senior consultant with The Greeley Company in Danvers, Massachusetts. That will highlight your efforts for surveyors.

In a blog post on HCPro's "Mac's Safety Space," MacArthur says integrating the EID threats into infection control sections of your HVA might mask evidence of your attention to these threats. If so, you might be pressed into breaking out those integrated items later, and it will be easier to just keep them separate.

#### **CDC** recommendations

The CDC bulletin outlines a number of recommended actions, including planning for initial triage of potential patients or patients under investigation (PUI). It writes:

"Here are the steps that facilities should implement as a routine part of triage to quickly identify, isolate, and inform public health authorities about patients who may have communicable infections:

- Ask about and document international travel histories at initial triage. This information can alert
  healthcare personnel to the possibility of communicable infections, such as viral hemorrhagic fevers or emerging respiratory viruses, and other health conditions, such as malaria, that need specific treatment.
- Identify patients who have fever and other signs and symptoms of infection and might warrant isolation pending further evaluation.
- Post contact information in easily visible locations for infection control personnel and the local public health jurisdiction for reporting of communicable diseases."

The bulletin also says facilities already should have "established plans for how PUIs or EVD patients are to be managed and referred," and includes several online resources.

#### **CMS** echoes concerns

CMS' Quality, Safety and Oversight (QSO) Group issued the memo QSO19-06-ALL, "Emergency Preparedness — Updates to Appendix Z of the State Operations Manual (SOM)," on February 1. Appendix Z houses the interpretive guidelines for surveyors of all healthcare types in implementing the emergency preparedness *CoPs* that took effect in 2017.

Most of the revisions outlined in the Appendix Z update focus on emergency power. However, the initial emphasis in the CMS memo is on the agency's concerns about adding "emerging infectious diseases" to the current definition of the all-hazards approach to planning.

"After review, CMS determined it was critical for facilities to include planning for infectious diseases within their emergency preparedness program. In light of events such as the Ebola Virus and Zika, we believe that facilities should consider preparedness and infection prevention within their all-hazards approach, which covers both natural and man-made disasters," notes the memo.

In the Appendix Z revisions, under Tag E-0004, which requires healthcare organizations to use an all-hazards approach, CMS adds EIDs to examples of hazards it expects facilities to consider. It notes "these EIDs may require modifications to facility protocols to protect the health and safety of patients, such as isolation and personal protective equipment (PPE) measures."

Originally published in the May 2019 issue of Patient Safety Monitor Journal.

#### **CMS Revises Immediate Jeopardy Process**

Be prepared to be held accountable for actions by contractors, staff, or volunteers that result in noncompliance with CMS' *Conditions of Participation (CoP)* and put a patient in harm's way. Even if those actions are unintentional, your facility still could face a finding of immediate jeopardy (IJ).

In an effort to streamline its process and increase communication with providers, CMS has rewritten its guidance for surveyors on when and how to determine if an IJ finding exists.

There are now three key components that must be met for IJ to be called:

- Noncompliance with a single federal safety standard
- Evidence of harm or likelihood of harm
- The determination that there is an immediate need for action to prevent harm, or more harm, from occurring

In addition, before they leave the premises, surveyors must present a form listing the evidence for each component of the IJ decision.

The revisions, which apply to all provider types, were outlined in a memo to CMS state survey agencies from the Quality, Safety & Oversight (QSO) group. In QSO19-09-ALL, "Revisions to Appendix Q, Guidance on Immediate Jeopardy," issued March 5, 2019, CMS presented what it hopes is a more efficient process.

Surveyors were given until March 22 to complete the online training on the guidance, which is effective immediately.

Compliance experts hailed the changes that put more emphasis on cause and effect in associating *CoP* noncompliance with patient harm.

However, the policy also explicitly says hospitals and other facilities can be held accountable for a staffer's actions, warns **Ernest E. Allen, ARM, CSP, CPHRM, CHFM**, a patient safety account executive with The Doctors Company in Columbus, Ohio.

For example, a doctor in a Columbus hospital is being investigated for possibly prescribing overdoses of opioids to near-death patients, more than two dozen of whom died, according to media reports. The doctor was fired in January and had his medical license suspended, pending investigation, while more than 20 nurses and pharmacists were put on leave. In February, CMS declared an IJ situation at the hospital, accepted a plan of correction, and removed the IJ after later inspections.

"In my opinion, this new policy takes that [kind of situation] into consideration," says Allen. He points to a section of the revised guidance that states the following:

"Please note, in determining noncompliance an entity may state that they properly trained and supervised individuals and that it was a 'rogue' employee that violated a regulation. If this occurs, it should be cited as noncompliance despite an entity's compliance efforts to train and monitor the employee. An entity cannot disown the acts of its employees, operators, consultants, contractors, or volunteers or disassociate itself from the consequences of their actions to avoid a finding of noncompliance."

#### Revisions create core guidance

The original 34-page Appendix Q, written in 2004, relied heavily on examples taken from nursing homes and other long-term care facilities.

The appendix now is broken out into a 12-page Core Appendix Q, plus subparts to address unique conditions found in long-term care facilities (nursing and skilled nursing facilities) and laboratories that operate under regulations set by the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

By breaking out those subparts and creating a mandatory two-page IJ template, CMS is telling surveyors it hopes the revisions can help them do a better job of determining IJ and communicating problems to healthcare providers so they can "more quickly address and correct identified concerns."

#### Some changes welcome

Among other major revisions to the IJ process, surveyors will no longer determine if culpability was involved. Also, there must be a clear cause-and-effect relationship between the noncompliance and the serious harm or likelihood of harm. CMS is telling surveyors, "To determine that IJ exists, it's not sufficient to simply say, 'Here's some harm that has occurred and here's some noncompliance,' " according to online training CMS published along with a memo outlining the changes.

It's a key change that will be welcome, particularly by hospitals, notes **Jennifer Cowel, RN, MHSA,** CEO of Patton Healthcare Consulting and a former director of service operations for The Joint Commission (TJC).

"The revisions clearly state that you cannot call IJ simply because there is a potential for serious harm," she says. "Now, under the revised guidelines there has to be a likelihood for a serious adverse outcome as a result of the situation. A reasonable person has to determine a serious event is a likelihood. We have seen IJ called when it was a mere 'potential' for harm, but harm may not have been a likelihood."

The revisions include definitions of key terms, including "likely" and "likelihood of harm." They state: "Likely/Likelihood means the nature and/or extent of the identified noncompliance creates a reasonable expectation that an adverse outcome resulting in serious injury, harm, impairment, or death will occur if not corrected."

#### 'Reasonable person' concept in use

Notably, however, the revised appendix does not define what constitutes a "reasonable expectation." In the online training, CMS acknowledges that although applying the "reasonable person" concept to determine harm has been the standard in long-term care settings, it is a significant change in IJ guidance for other provider types.

The training says the concept is particularly necessary when noncompliance with a standard results in no physical harm, such as injury or death, but when surveyors nevertheless determine an IJ situation exists for psychosocial harm on a recipient of care after applying the "reasonable person" concept.

"The reasonable person approach considers how a reasonable person in the recipient's position would be impacted by the noncompliance," according to CMS.

"When they clarify that 'likelihood' is synonymous with reasonable expectation, it still distances itself from calling an IJ just for a remote possibility of harm," says Cowel, noting that the memo includes an expectation that state surveyors will participate in online education.

CMS' revisions "challenge the surveyor," says Cowel, "and state the surveyor must reasonably expect a specific serious adverse outcome is likely to occur if immediate action is not taken."

#### **Impact unclear**

While the revisions may offer a clearer understanding of the process, consultants say, this doesn't necessarily mean anything will be easier (or more difficult) for providers. And it's still unclear how the revisions will impact the process by which accrediting organizations determine IJ, or how often they will do so.

Despite the revisions clarifying the meaning of certain terms, the reality is IJ findings occur infrequently in hospitals, notes **Kurt Patton**, **MS**, **RPh**, former director of accreditation services for TJC and founder of Patton Healthcare Consulting in Naperville, Illinois.

TJC now is focused primarily on infection control issues when determining a preliminary denial of accreditation, TJC's version of IJ. CMS focuses more on patient rights issues, including restraint and seclusion problems or patient grievances, says Patton.

These events, he predicts, are where the discussion of "psychosocial harm" will come into play. "I would anticipate this being associated only with improper restraint and seclusion or direct abuse by staff, not the usual medical incidents," Patton says.

Determining such harm could prove problematic for providers, says Allen. "I think this will make things harder and more strict regarding deficiency findings on CMS and Joint Commission surveys," he notes. "The new 'psychosocial harm' in my opinion is surveyor-dependent and hard for a hospital to dispute."

The CMS surveyor training notes that psychosocial harm can particularly apply to patients with impaired cognitive function: "Suppose someone is the victim of sexual exploitation: naked pictures were taken of this individual, but due to cognitive impairment, the person was unable to appreciate the gravity of the harm done. If we apply the 'reasonable person' concept, we're likely to determine that a reasonable person would be mortified to be disrobed and exploited in that way. We can then more accurately gauge the seriousness of the psychosocial harm this person suffered."

#### 'Culpability' no longer a factor

CMS emphasizes in the memo introducing the revisions that the term "culpability" has been removed from the IJ equation.

The memo states: "The previous version of Appendix Q made culpability a required component to cite immediate jeopardy. Because the regulatory definitions of immediate jeopardy do not require a finding of culpability, that requirement has been removed and has been replaced with the key component of non-compliance, since the definitions of immediate jeopardy require noncompliance to be the cause of the serious injury, harm, impairment or death, or the likelihood thereof."

Providers are likely to welcome the change.

"That term was unusual as it requires blameworthiness," says Patton. "In reality in your hospital, if a patient is injured due to noncompliance, blameworthiness of the organization is immaterial. Blameworthiness is more pertinent in analyzing staff behaviors associated with an adverse event. Did they follow policy, did the system lead them to the error, or did they recklessly disregard safety policies? Blameworthiness is meaningful for the individual, not so for the organization."

Originally published in the May 2019 issue of Briefings on Accreditation & Quality.

#### Review Hospital Policies After Suicide Risk NPSG Clarified in Updated FAQs

Find people at your organization who can review your suicide risk reduction policies from a new perspective now that both The Joint Commission (TJC) and CMS have updated expectations.

TJC this May released clarifying information on its suicide risk reduction National Patient Safety Goal (NPSG), effective July 1, 2019. The clarifications cover risk factors to ask about during suicide assessments and protective factors to enact. It also clarifies that universal suicide screening isn't required.

And CMS in April asked for public comment on proposed changes to how its regional surveyors assess patient harm in hospitals.

**Jennifer Cowel, RN, MHSA,** president of Patton Healthcare Consulting in Naperville, Illinois, says that all facilities should review their policies in wake of these changes.

"Since the updated NPSG on ligature goes live this summer and these new FAQs were just published, it is a great time to send these both to the team responsible for the policy and procedures and training on ligature, self-harm, and suicide," she says. "There is an actually new detail in the FAQs that may or may not be in a hospital's policy at present because the NPSGs were not as clear as these FAQs in a couple areas."

Involve staff who may be able to offer a new perspective.

"Take a fresh set of eyes. Review the FAQs, the new NPSG, and the draft CMS memo," says Cowel. "With fresh eyes, review the hospital's own policy, procedures, screening, and assessment tools to see if you are meeting all of the new expectations."

#### **Assessing risk factors**

Element of performance (EP) 3 for NPSG 15.01.01 requires that the suicide risk assessment include risk factors, which TJC describes as "a combination of individual, biological, psychological, familial, community, cultural, and/or societal characteristics or factors that may contribute to the risk of suicide."

According to the first of the new FAQs, examples of suicide risk factors include:

- Family history of suicide
- Family history of child maltreatment
- Previous suicide attempt(s)
- History of mental disorders, particularly clinical depression
- History of alcohol and substance abuse
- Feelings of hopelessness

- Impulsive or aggressive tendencies
- Cultural and religious beliefs (e.g., belief that suicide is noble resolution of a personal dilemma)
- Local epidemics of suicide
- Isolation, a feeling of being cut off from other people
- Barriers to accessing mental health treatment
- Loss (relational, social, work, or financial)
- Physical illness
- Easy access to lethal methods
- Unwillingness to seek help because of the stigma attached to mental health and substance abuse disorders or to suicidal thoughts

In the assessment FAQ, TJC made it clear that you need to use an evidence-based assessment tool and the clinical evaluation of a provider, says Cowel.

"We have seen hospitals have nurses do a proper screen and then have the LIPs make a judgment call about suicide risk based only on a clinical assessment," which is the wrong way to do things, she says.

"Review the procedure the physician or LIP follows," she says. "LIPs need to understand this is a two-part assessment, and they need to be actually doing and documenting the results of this assessment in the patient's record."

Every assessment has to result in a determination of the level of suicide risk (e.g., high, moderate, or low). It's not good enough to have the LIP discontinue 1:1 observation without documenting the assessment's results.

"Likewise, if the patient is determined to be at risk of suicide, the LIP documentation has to identify the plan to mitigate the risk," says Cowel. "This could include 1:1 for high-risk patients or something less than 1:1 for low- and/or moderate-risk patients."

When it comes to TJC's list of risk factors, these are things that should be assessed after a patient screens positive for suicide risk. After all, there's no screener that can accurately score "cultural or religious beliefs" or "local epidemics of suicide."

"The suicide screen is a [simpler] assessment using an evidence-based tool, and frontline caregivers can be trained to do a screen," she says. "Following the screen, the more thorough suicide assessment has to be completed using an evidence-based assessment tool along with a clinical evaluation. The clinical evaluation should consider risk factors, such as the two you mention above, and protective factors."

#### Tools can't be modified randomly

You need an evidence-based tool for screening suicidal ideation, one that's appropriate for your setting and patient population, says Cowel.

The Joint Commission has identified examples of validated screening tools. One of them is the PHQ-9, which Cowel has seen used as the only screening tool in some hospitals. The other one, which Cowel strongly recommends, is the Columbia-Suicide Severity Rating Scale (C-SSRS). It can be used for both the screening and the assessment that follows the screening.

"There is a reassessment tool as part of the suite of Columbia tools that can be used for any reassessments done after the original assessment," she says. "Finally, the Columbia Lighthouse Project offers a tool titled the SAFE-T risk assessment tool with C-SSRS questions embedded and triage categories. Review it as you review options."

However, as you weigh your options, remember that all evidence-based tools have undergone rigorous testing and studying to develop. You can't just take some new questions and throw them into the mix, Cowel notes. You have to adopt the screener as published.

"It is not acceptable to pick an evidence-based tool such as the Columbia C-SSR tool or the PHQ-9 tool and then modify the wording in the questions at all," she says. "The FAQ states that if you alter the wording on the screen, it is no longer considered evidence-based."

It's also important to consider age when screening for suicidal ideation, she says. The questions you ask an adult may not be suited for use on a child or teenager.

"We see hospital EDs with a policy to screen adults 18 years of age and older," she says. "This totally leaves the adolescent vulnerable population without screening."

There are screening tools that are valid for younger patients, like the Ask Suicide-Screening Questionnaire for children ages 12–17. Make sure your policy lists the tools and procedures for when a teenager or child comes into your ED with suicidal ideation.

#### **Protective factors**

TJC also posted an FAQ about assessing protective factors, which EP 3 requires the suicide risk assessment to include. Protective factors are "characteristics associated with a lower likelihood of negative outcomes or that reduce a risk factor's impact. Protective factors may buffer individuals from suicidal thoughts and behaviors," according to the FAQ.

Examples of protective factors include:

- Safe, secure, monitored environment (e.g., inpatient hospitalization)
- Receiving clinical care for mental, physical, and substance abuse disorders
- Easy access to a variety of clinical interventions and support for help-seeking
- Family and community support (connectedness)
- Support from ongoing medical and mental healthcare relationships
- Skills in problem solving, conflict resolution, and nonviolent ways of handling disputes
- Cultural and religious beliefs that discourage suicide and support instincts for self-preservation

#### Not universal

The third FAQ clarified that suicide screening is not required for all patients. The NPSG "does not require organizations to universally screen all patients for suicidal ideation," according to the FAQ. "Screening patients for suicide risk with secondary diagnoses or secondary complaints of emotional or behavioral disorders is encouraged but not required."

There's nothing new about this, says Cowel. You only need to screen a patient when he or she is in an acute care setting and being primarily evaluated or treated for behavioral health conditions.

"That said, the FAQ strongly encourages hospital to consider screening patients with secondary diagnoses or secondary complaints of emotional or behavioral disorders," she adds.

Facilities can choose whether they want to perform universal suicide screening. Cowel says when making that decision, each facility would need to assess the population they serve (inpatient and outpatient) to determine whom they will screen outside of the required group.

"I do support screening patients with a secondary complaint of emotional or behavioral disorder," Cowel says.

The FAQ specifically states that clinicians treating patients for medical conditions should be aware that the patients "may also have behavioral tendencies that, if triggered, may lead to self-harm. For example, changes in health status resulting in a poor prognosis, chronic pain resulting from injury or illness, etc. Psychosocial changes, such as sudden loss of a loved one, broken relationships, financial hardship, etc., can also trigger self-harm behaviors. These patients may also be at risk for suicide, therefore, it is important for clinicians to properly assess these individuals for suicidal ideation as part of their overall clinical evaluation, when indicated."

Originally published in the July 2019 issue of **Inside Accreditation & Quality**.

#### **New Compounding Pharmacy Certification Designed to Boost Compliance**

Consider getting an accrediting organization to review and certify your hospital's drug compounding practices as scrutiny ratchets up on medication management of both sterile and hazardous drugs.

CMS' *State Operation Manual*, Appendix A (SOMA), which provides its surveyors interpretive guidance on enforcing the *Conditions of Participation (CoP)*, requires hospitals to show that their drug compounding practices are equivalent to—or more stringent than—the standards set out by the United States Pharmacopeial Convention.

The SOMA cites both *USP General Chapter* < 795 > *Pharmaceutical Compounding—Nonsterile Preparations and General Chapter* < 797 > *Pharmaceutical Compounding—Sterile Preparations.* Most recently, expanded guidance after USP < 797 > was updated in 2017 in the wake of several deaths related to sterile compounding failures.

And CMS surveyors are checking closely on specifics.

In January, a hospital in Worcester, Massachusetts was cited under Tag A-0501, Pharmacist Supervision of Services, for a number of deficiencies at their compounding pharmacy department, including:

- Sprinkler covers that were not flush to the ceiling, leaving a "crack of space observed between ceiling and hanging sprinkler covers"
- A dirty floor "indicated by the appearance of hair strands located to the left of the Compounding Aseptic Containment Isolator (CACI)"
- Chipped paint on the lower edge of a wall near the CACI
- A lack of daily pressure monitoring "either by daily log or continuous recording device" between the ante area of the compounding room where staff were to put on their protective garb and the pharmacy department itself
- A lack of documentation "of minimum displacement airflow of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area (open architecture design requirement)" for one of the days preceding the survey
- Failure to follow the hospital's own waste disposal policy using color-coded bins

While the standards of all four CMS-approved hospital accrediting organizations must adhere to the *CoP*, only two have additional compounding certifications. The Joint Commission launched its Medication Compounding Certification in 2017, followed by HFAP's (Healthcare Facilities Accreditation Program) Compounding Pharmacy Certification in 2018.

In a news release announcing its program in December 2018, HFAP's **Marci Ramahi**, **CAE**, director of accreditation/certification operations, noted that while the certification was not required for accreditation, the program "aims to instill best practices into everyday activities, ensuring pharmacies and specialized pharma products meet the highest standards of quality."

Adhering to higher standards will not only help hospitals meet CMS drug compounding expectations but can better prepare hospitals and their pharmacy operations as newer requirements become effective for the handling and disposal of drugs considered hazardous to both humans and the environment, Ramahi tells *Inside Accreditation and Quality*.

USP General Chapter < 800 > Hazardous Drugs—Handling in Healthcare Settings is effective December 1. While that chapter sets requirements for protecting staff during the handling of hazardous drugs, a new final rule from the EPA published in February sets out new regulations on the disposal of drugs hazardous to the environment. (For background, see *Inside the Joint Commission*, *3/4/19*.)

HFAP will be updating its standards as new requirements are adopted. The USP is revising both USP <795 > and <797 > this year. And HFAP will update its certification requirements once <800 > becomes effective, says Ramahi.

Pharmacy compounding requirements and safe medication practices have long been outlined in HFAP's manual on *Accreditation Requirements for Acute Care Hospitals*, especially in the Nursing Department and Pharmacy/Medication Use chapters, notes Ramahi.

But now, new science and new standards are changing practices, she says.

The Compounding Pharmacy Certification was created to help hospitals navigate the growing concerns and requirements regarding drug management. The 140-page certification manual covers various requirements, from expectations of leadership to provide a safe environment and oversee infection control, to the specifics of the physical environment including cleaning materials and practices, to staff training and patient education, to quality control and performance improvement activities.

While the pharmacy leadership should be driving compliance with drug handling requirements, Ramahi stresses it takes a multidisciplinary team to ensure safe practices overall.

That team must include nursing, because they are responsible for point of care, as well as facilities management, which must tackle air pressure relationships, repairs, and maintenance issues. And of course, the overall hospital leadership must be involved because "generally, when you start talking about changes like this, it does take resources, time, and money," says Ramahi.

It also takes planning, especially if major construction is involved.

"It's always a challenge to make changes in a facility," says Ramahi. "If they have to change the air handling system, it's a pretty big project."

But organizations must also pay attention to the details, she says.

While overall HFAP looks for organizations "to take a holistic approach and not have everything in siloes," says Ramahi, the requirements for pharmacies and compounding tend to be "much more granular." With that, expect surveyors to be asking about compliance with a specific standard.

Here are some common challenges to watch out for, according to Ramahi:

- Be aware of every location where compounding of drugs may occur. During a recent survey, a hospital's main compounding pharmacy did well in meeting requirements, but an off-campus location did not fare so well. Remote locations "may not get as much attention," Ramahi says. Ensure good communication with the nursing leadership because compounding is often done by nursing staff at the point of care.
- Expect to need more resources for hazardous drugs and materials. The certification requirements do not cite USP < 800 > now, but they still outline several key concerns about the use and handling of hazardous drugs and other hazardous materials used as part of the compounding process. That includes not just the personal protective equipment needed by staff, but airflow requirements during processing, as well as staff training in use and precautions, the availability of safety data sheets (SDS) as required by OSHA, and the proper handling and disposal of hazardous materials and drugs.
- Pay close attention to your infusion centers. Medications used at infusion centers must be properly packaged, transported, and stored until administration, and the requirements can get very technical, notes Ramahi. "The policies and procedures become very important," as do "the training on policies and procedures."
- When changes are made, ensure everyone is educated on those changes. "People get used to doing something one way," says Ramahi, and it's important staff understand when and how practices change.
- Ensure compounding pharmacy staff can demonstrate competency in their given tasks. Compounding pharmacy training is very specific, and you must test staff's competency—surveyors can and will ask for demonstrations, warns Ramahi. Competency must be built into the training.
- Maintain a current inventory of drugs. Hospitals must be aware of the drugs they use that are on the CDC's National Institute for Occupational Safety and Health (NIOSH) list of antineoplastic and other hazardous drugs. The current list is from 2016 but is being updated. And staff must be aware of the drugs they are handling and the documented risks for each drug, notes Ramahi.

While the upcoming requirements on hazardous drugs and materials, both in use and disposal, are not currently specified, hospitals must be aware they are upcoming.

"They should be doing self-assessments where they may not be meeting the guidelines and coming up with a plan of action," advises Ramahi, "building that into planning."

Remember also that surveyors will be looking at hospital policies and procedures, and "they'll be asking staff for their ability to access local, state, and federal regulations—we do expect every hospital to be aware of their local regulations, for example transporting hazardous materials," says Ramahi.

Surveyors may also ask where a hospital is getting the information on which the policies and procedures are based, possibly posing the question to frontline staff. "If they are handling a product that has an SDS, then they should know how to access that. And it should be readily available."

Find the various compounding standards at *www.usp.org/compounding*. Find the NIOSH hazardous drugs list at *www.cdc.gov/niosh/docs/2016-161/default.html*.

Originally published in the August 2019 issue of Inside Accreditation & Quality.

#### **How to Track Updates**

CMS provides the following instructions for tracking updates on the CMS website under Regulations and Guidance (www.cms.hhs.gov):

- Each appendix is a separate file that can be accessed directly from the SOM Appendix Table of Contents, as applicable.
- The appendixes are in PDF format, which is the format generally used in the SOM to display files. Click on the red button in the Download column to download a copy of any available file in PDF format.
- To return to this page after opening a PDF file on your desktop, use your browser's "back" button, because closing the file will also close most browsers.

The following is a list of several CMS Web pages and instructions on how they are of use:

- For tracking updates, refer to the CMS State Survey and Certification page, located at <a href="https://www.cms.hhs.gov/SurveyCertificationGenInfo">www.cms.hhs.gov/SurveyCertificationGenInfo</a>. Everyone should check this page monthly for updates—appoint someone to do so. This page contains CMS survey and certification memoranda, guidance, clarifications, and instructions to state survey agencies and CMS regional offices. It is searchable by date and keyword.
- The CMS Transmittals page also provides information on important issues (*www.cms.hhs.gov/transmittals*). According to the CMS website, program transmittals are used to communicate new or changed policies and/or procedures that are being incorporated into a specific CMS program manual. The cover page (or transmittal page) summarizes the new and changed material, specifying what has been changed.
- If you are working in a hospital setting, another good place to check for updates includes CMS' Hospital Center page, which can be found at <a href="https://www.cms.hhs.gov/center/hospital.asp">www.cms.hhs.gov/center/hospital.asp</a>. Most of the announcements this year have been related to payment systems, but accreditation-related changes are also announced here.
- The EMTALA page (*www.cms.hhs.gov/EMTALA*) should also be checked. On this page, you will find updates to regulations, manuals, and appendixes, and links back to transmittals related to EMTALA and EMTALA survey and certification letters. There is also a series of links to additional material.

# State Operations Manual Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

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(Rev. 183, 10-12-18)

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#### **Survey Protocol**

#### Introduction

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

Hospitals are required to be in compliance with the Federal requirements set forth in the Medicare Conditions of Participation (CoP) in order to receive Medicare/Medicaid payment. The goal of a hospital survey is to determine if the hospital is in compliance with the CoP set forth at 42 CFR Part 482. Also, where appropriate, the hospital must be in compliance with the PPS exclusionary criteria at 42 CFR 412.20 Subpart B and the swing-bed requirements at 42 CFR 482.66

Certification of hospital compliance with the CoP is accomplished through observations, interviews, and document/record reviews. The survey process focuses on a hospital's performance of patient-focused and organizational functions and processes. The hospital survey is the means used to assess compliance with Federal health, safety, and quality standards that will assure that the beneficiary receives safe, quality care and services.

#### **Regulatory and Policy Reference**

- The Medicare Conditions of Participation for hospitals are found at <u>42CFR Part</u> 482.
- Survey authority and compliance regulations can be found at <u>42 CFR Part 488</u> Subpart A.
- Should an individual or entity (hospital) refuse to allow immediate access upon reasonable request to either a State Agency or CMS surveyor, the Office of the Inspector General (OIG) may exclude the hospital from participation in all Federal healthcare programs in accordance with 42 CFR 1001.1301.
- The regulatory authority for the photocopying of records and information during the survey is found at 42 CFR 489.53(a)(13).
- The CMS State Operations Manual (SOM) provides CMS policy regarding survey and certification activities

Surveyors assess the hospital's compliance with the CoP for all services, areas and locations in which the provider receives reimbursement for patient care services billed under its provider number.

Although the survey generally occurs during daytime working hours (Monday through Friday), surveyors may conduct the survey at other times. This may include weekends and times outside of normal daytime (Monday through Friday) working hours. When the survey begins at times outside of normal work times, the survey team modifies the survey, if needed, in recognition of patients' activities and the staff available.

All hospital surveys are unannounced. Do not provide hospitals with advance notice of the survey.

#### **Tasks in the Survey Protocol**

Listed below, and discussed in this document, are the tasks that comprise the survey protocol for hospital.

Task 1	Off-Site Survey Preparation
Task 2	Entrance Activities
Task 3	Information Gathering/ Investigation
Task 4	Preliminary Decision Making and Analysis of Findings
Task 5	Exit Conference
Task 6	Post-Survey Activities

#### **Survey Modules for Specialized Hospital Services**

The modules for PPS-exempt units (psychiatric and rehabilitation), psychiatric hospitals, rehabilitation hospitals and swing-bed hospitals are attached to this document. The survey team is expected to use all the modules that apply to the hospital being surveyed. For example, if the hospital has swing-beds, a PPS excluded rehabilitation unit, and a PPS excluded psychiatric unit, the team will use those three modules in addition to this protocol to conduct the survey. If the hospital is a rehabilitation hospital, the team will use the rehabilitation hospital module in addition to this protocol to conduct the survey. If the hospital is a psychiatric hospital and if the survey team will be assessing the hospital's compliance with both the hospital CoPs and psychiatric hospital special conditions, the team will use the psychiatric hospital module in addition to this protocol to conduct the survey.

#### **Survey Team**

#### **Size and Composition**

The SA (or the RO for Federal teams) decides the composition and size of the team. In general, a suggested survey team for a full survey of a mid-size hospital would include two-four surveyors who will be at the facility for 3 or more days. Each hospital survey team should include at least one RN with hospital survey experience, as well as other surveyors who have the expertise needed to determine whether the facility is in compliance. Survey team size and composition are normally based on the following factors:

- Size of the facility to be surveyed, based on average daily census;
- Complexity of services offered, including outpatient services;
- Type of survey to be conducted;
- Whether the facility has special care units or off-site clinics or locations;
- Whether the facility has a historical pattern of serious deficiencies or complaints; and
- Whether new surveyors are to accompany a team as part of their training.

#### **Training for Hospital Surveyors**

Hospital surveyors should have the necessary training and experience to conduct a hospital survey. Attendance at a Basic Hospital Surveyor Training Course is suggested. New surveyors may accompany the team as part of their training prior to completing the Basic Hospital Surveyor Training Course.

#### **Team Coordinator**

The survey is conducted under the leadership of a team coordinator. The SA (or the RO for Federal teams) should designate the team coordinator. The team coordinator is responsible for assuring that all survey preparation and survey activities are completed within the specified time frames and in a manner consistent with this protocol, SOM, and SA procedures. Responsibilities of the team coordinator include:

- Scheduling the date and time of survey activities;
- Acting as the spokesperson for the team;
- Assigning staff to areas of the hospital or tasks for the survey;
- Facilitating time management;
- Encouraging on-going communication among team members;
- Evaluating team progress and coordinating daily team meetings;
- Coordinating any ongoing conferences with hospital leadership (as determined appropriate by the circumstances and SA/RO policy) and providing on-going feedback, as appropriate, to hospital leadership on the status of the survey;
- Coordinating Task 2, Entrance Conference;
- Facilitating Task 4, Preliminary Decision Making;
- Coordinating Task 5, Exit Conference; and
- Coordinating the preparation of the Form CMS-2567.

#### Task 1 - Off-Site Survey Preparation

#### **General Objective**

The objective of this task is to analyze information about the provider in order to identify areas of potential concern to be investigated during the survey and to determine if those

areas, or any special features of the provider (e.g., provider-based clinics, remote locations, satellites, specialty units, PPS-exempt units, services offered, etc.) require the addition of any specialty surveyors to the team. Information obtained about the provider will also allow the SA (or the RO for Federal teams) to determine survey team size and composition, and to develop a preliminary survey plan. The type of provider information needed includes:

- Information from the provider file (to be updated on the survey using the Hospital/CAH Medicare Database Worksheet), such as the facility's ownership, the type(s) of services offered, any prospective payment system (PPS) exclusion(s), whether the facility is a provider of swing-bed services, and the number, type and location of any off-site locations;
- Previous Federal and state survey results for patterns, number, and nature of deficiencies, as well as the number, frequency, and types of complaint investigations and the findings;
- Information from CMS databases available to the SA and CMS. Note the exit date of the most recent survey;
- Waivers and variances, if they exist. Determine if there are any applicable survey directive(s) from the SA or the CMS Regional Office (RO); and
- Any additional information available about the facility (e.g., the hospital's Web site, any media reports about the hospital, etc).

#### **Off-Site Survey Preparation Team Meeting**

The team should prepare for the survey offsite so they are ready to begin the survey immediately upon entering the facility. The team coordinator should arrange an off-site preparation meeting with as many team members as possible, including specialty surveyors. This meeting may be a conference call if necessary.

During the meeting, discuss at least the following:

- Information gathered by the team coordinator;
- Significant information from the CMS databases that are reviewed;
- Update and clarify information from the provider file so a surveyor can update the Medicare database using the "Hospital/CAH Medicare Database Worksheet," Exhibit 286;
- Layout of the facility (if available);
- Preliminary team member assignments;

- Date, location and time team members will meet to enter the facility;
- The time for the daily team meetings; and
- Potential date and time of the exit conference.

Gather copies of resources that may be needed. These may include:

- Medicare Hospital CoP and Interpretive Guidelines (Appendix A);
- Survey protocol and modules;
- Immediate Jeopardy (<u>Appendix Q</u>);
- Responsibilities of Medicare Participating Hospitals in Emergency Cases (<u>Appendix V</u>);
- Hospital Swing-Bed Regulations and Interpretive Guidelines (Appendix T);
- Hospital/CAH Medicare Database Worksheet, Exhibit 286;
- Exhibit 287, Authorization by Deemed Provider/Supplier Selected for Accreditation Organization Validation Survey; and
- Worksheets for swing-bed, PPS exclusions, and restraint/seclusion death reporting.

#### Task 2 - Entrance Activities

#### **General Objectives**

The objectives of this task are to explain the survey process to the hospital and obtain the information needed to conduct the survey.

#### **General Procedures**

#### Arrival

The entire survey team should enter the hospital together. Upon arrival, surveyors should present their identification. The team coordinator should announce to the Administrator, or whoever is in charge, that a survey is being conducted. If the Administrator (or person in charge) is not onsite or available (e.g., if the survey begins outside normal daytime Monday-Friday working hours), ask that they be notified that a survey is being conducted. Do not delay the survey because the Administrator or other hospital staff is/are not on site or available.

#### **Entrance Conference**

The entrance conference sets the tone for the entire survey. Be prepared and courteous, and make requests, not demands. The entrance conference should be informative, concise, and brief; it should not utilize a significant amount of time. Conduct the entrance conference with hospital administrative staff that is available at the time of entrance. During the entrance conference, the Team Coordinator should address the following:

- Explain the purpose and scope of the survey;
- Briefly explain the survey process;
- Introduce survey team members, including any additional surveyors who may join the team at a later time, the general area that each will be responsible for, and the various documents that they may request;
- Clarify that all hospital areas and locations, departments, and patient care settings
  under the hospital provider number may be surveyed, including any contracted
  patient care activities or patient services located on hospital campuses or hospital
  provider based locations;
- Explain that all interviews will be conducted privately with patients, staff, and visitors, unless requested otherwise by the interviewee;
- Discuss and determine how the facility will ensure that surveyors are able to obtain the photocopies of material, records, and other information as they are needed;
- Obtain the names, locations, and telephone numbers of key staff to whom questions should be addressed;
- Discuss the approximate time, location, and possible attendees of any meetings to be held during the survey. The team coordinator should coordinate any meetings with facility leadership; and
- Propose a preliminary date and time for the exit conference.

During the entrance conference, the Team Coordinator will arrange with the hospital administrator, or available hospital administrative supervisory staff if he/she is unavailable to obtain the following:

- A location (e.g., conference room) where the team may meet privately during the survey;
- A telephone for team communications, preferably in the team meeting location;

# The CMS Hospital Conditions of Participation and Interpretive Guidelines

2020 Edition

Compliance with the *Conditions of Participation (CoP)* is required to meet Medicare and Medicaid hospital regulations. While CMS posts updates to the *CoP*s on its website, they are often difficult to search and lengthy, not to mention tedious to print.

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- Includes the most recent CoP IGs from CMS
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- Includes CMS survey protocol

CMS updates the *CoPs* a few times a year. This new edition will contain the most recent *CoPs* and Survey and Certification memos, which include new requirements and clarifications on Immediate Jeopardy, ligature risk, and emerging infectious diseases.

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