POLICYMEDICAL

ISSUE 3

Regulations Roundup

The Latest News in Healthcare Regulations and Standards

IN THIS ISSUE

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THE JOINT COMMISSION (TJC) AND YOU

TJC Revises Decision Rules and the Post-Survey Process

Is your organization up for reaccreditation by TJC? You need to know that some decision rules and processes post-survey have changed.

TJC has made some changes to the post-survey process and decision rules for accreditation that are meant to simplify surveys and their outcome. The changes are currently in effect and **apply to all organizations seeking reaccreditation**.

Decision Rules

1. *Accreditation with Follow-up Survey*: a notice of full accreditation will be given to an organization with this decision as soon as it successfully submits Evidence of Standards Compliance (ESC). A follow-up survey must be conducted within six months to confirm that the organization has sustained compliance with the ESC.
2. *Contingent Accreditation*: this category has been **eliminated**
3. *Preliminary Denial of Accreditation (PDA)*: new decision rules have been added to this category:
   i. PDA06 – this will be given when an organization that has a decision of Accreditation with Follow-up Survey fails to resolve all Requirements for Improvement (RFIs) after two (2) opportunities to submit ESCs
   ii. PDA09 – if an organization fails its second Medicare follow-up survey due to scoring Condition-level deficiency on one or more Conditions of Participation or Conditions of Coverage, it will be given a PDA09 decision
   iii. PDA10 – this decision will be granted when there is evidence that an organization may have engaged in possible fraud or abuse leading to patients being placed at risk for a serious adverse outcome.

Get full details of all the decision rules for 2017 from your *Joint Commission Connect™* extranet in the 'What's New' section.

Post-Survey Process

1. *PDA02 decision*: an organization receives this decision when patients may have been placed at risk for serious adverse outcomes because of patterns, trends, and/or repeat findings. If an organization receives a PDA02 decision, it is now required to **submit a Plan of Correction (POC) within ten (10) business days** of the posting of the final report **INSTEAD of submitting an ESC within 60 days**.

   A validation survey will be conducted within two (2) months to verify that the POC has been implemented and if it has not been implemented, the PDA decision will stand and the organization can seek an appeal.

2. *Accreditation Decision Making*: this will no longer be the responsibility of an Accreditation Committee. These decisions will now be made by an executive team of TJC leaders who will also be responsible for deliberating on survey reports, follow-up activities, staff recommendations, and unusual or unique issues raised by an organization seeking to be accredited by TJC.

The changes in the process for PDA02 decisions can be found on your *Joint Commission Connect™* extranet in the 'Important Updates' section.

These changes can result in added pressure to meet regulatory guidelines. Without proper structures in place, meeting a timeline of 10 business days to submit a POC will be difficult. To make the process easier, ensure there is a team in place that is responsible for leading this process. Additionally, having automated processes to manage documents – policies, procedures, standards, and regulations – is beneficial, as all documents will be easily accessible to all staff, and teams can work collaboratively to develop and update documents as required, among other benefits.

Safety Issue: Crash Cart Preparedness

What are your organization's policies governing crash carts and their readiness for use?

TJC has identified crash-cart preparedness as a safety issue and lists some factors relating to crash carts that contribute to patient safety events:

- Medication errors and mix-up
- Missing, expired, damaged, contaminated, and unavailable equipment or medications
- Empty oxygen tanks
- Staff unable to locate cart
- Staff not familiar with procedures for using the crash cart

TJC considers crash carts to be high risk medical equipment and as such, standard EC.02.04.01 which speaks to managing medical equipment risks should be referenced when addressing crash carts. Other standards that affect crash carts are EC.02.04.03 (inspecting, testing and maintaining medical equipment) and PC. 02.01.11 (resuscitation services).

Ensure your crash cart is ready for an emergency - **do your risk assessment, develop an action plan, train staff, implement the plan, and reassess**. Read TJC's Quick Safety advisory for guidance.

THE US DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare and Medicaid Services (CMS) Matters

FY2018 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Acute Care Hospital (LTCH) Prospective Payment System (PPS) Proposed Rule, and Request for Information (RFI)

The CMS has proposed numerous changes to the IPPS and LTCH PPS for the 2018 fiscal year (FY) and has also issued a RFI to gather ideas and suggestions on ways to improve the health care delivery system, including the Medicare program. A few of the many areas to be affected are:

- National Accrediting Organizations to be required to publish survey reports and plans of corrections from providers and suppliers of CMS-approved accreditation programs on their websites.
- Payment rates under IPPS – projections are for a total increase of 2.9% in IPPS operating payments and a $3.1 billion increase in Medicare payments on inpatient services including capital expenditure.
- Medicare uncompensated care payments - approximately $7 billion will be distributed in uncompensated care payments in FY 2018, almost $1 billion more than amounts for FY 2017. CMS is also proposing to begin incorporating uncompensated care cost data from Worksheet S-10 of the Medicare cost report into the approach to funds distribution for FY 2018 (Worksheet S-10 data for FY 2014 will be used for 2018, combined with insured low income days data from the two preceding cost reporting periods).

With CMS now deciding to begin using data from Worksheet S-10, providers should consider working with Medicare Administrative Contractors to review, revise and correct any errors in FY 2014 Worksheet S-10 data for submission to CMS as soon as possible. Additionally, providers need to conduct analyses of charity care and bad debt policies, gather data on charity care charge, disproportionate share and supplemental payments, and have proper documentation to support any amounts reported.

CMS has also issued a RFI to gather feedback and ideas on regulatory, sub-regulatory, policy, practice and procedural changes that can be implemented to help achieve program transparency, flexibility and innovation. Comments are welcomed up to **5:00 pm ET on Tuesday, June 13, 2017.** Get your copy of the proposed rule and RFI and read the fact sheet provided by the CMS for additional information.

Centers for Disease Control and Prevention (CDC) Corner

Updated Best Practice Guidelines for Immunizations

Do you have a policy addressing vaccinations for staff and patients?

On April 20, 2017, CDC published the *General Best Practice Guidelines for Immunizations Best Practice Guidelines of the Advisory Committee on Immunization Practices (ACIP)*. These guidelines update and replace the ACIP *General Recommendations on Immunization* last published in 2011. CDC advises that infants, children, adolescents and adults should be routinely vaccinated against 17 vaccine-preventable diseases and these guidelines provide best practices regarding issues such as timing of each dose, contraindications and precautions, altered immunocompetence, and interpreting and responding to adverse events.

Some of the major updates provided in the guidelines are documented below:

1. Latest information on simultaneous vaccination in the context of a risk for febrile seizures after administration of IIV and PCV_{13} vaccines in young children
2. Clarification of the use of the grace period between doses of MMRV
3. Inclusion of any condition that might confuse diagnostic accuracy in the definition of a "precaution"
4. Confirmation that vaccines should be administered to a hospitalized patient if they are not acutely moderately or severely ill
5. Protocols for managing anaphylactic allergy have been incorporated into the guidelines

CDC recommends that all health care workers be vaccinated against diseases such as hepatitis B, varicella, measles, mumps, rubella, and influenza, and the Joint Commission (TJC) has set standards surrounding vaccination in its infection prevention strategies. In TJC's Comprehensive Accreditation Manual for Hospitals (CAMH), standard IC.02.04.01 speaks to hospitals having an annual influenza vaccination program about which staff and independent contractors are educated and the influenza vaccine must be made available to all staff and independent contractors who work on-site. Standard IC.01.04.01, mandates that hospitals set goals to minimize the possibility of infections based on its identified risks. The CMS has outlined influenza and pneumococcal vaccination as inpatient measures in its Hospital Compare program.

Ensure you are using the latest information to guide your policies and procedures. CDC is offering continuing education (CE) credits (expiring April 20, 2019) to healthcare workers who participate in a course covering the updated guidelines. Information on obtaining CE credits can be found here. Stay informed, read the updated ACIP guidelines, participate in the course and obtain your CE credits.

US Food and Drug Administration (FDA)

Final Template for Clinical Trials Protocols now Available

Are you conducting phase 2 or 3 clinical trials that require investigational new drug or investigational device exemption? Do you receive funding from the NIH?

The FDA announced on May 2, 2017 that the FDA - National Institutes of Health (NIH) Joint Leadership Council has released the final version of a clinical trials protocol template that is designed to be used by investigators conducting phase 2 and phase 3 clinical trials that are funded by the NIH, and require investigational new drug (IND) or investigational device exemption (IDE) applications. It could however also be beneficial to investigators working on medical products that are not regulated by the FDA.

The electronic protocol writing tool provides a standardized format for investigators to use when putting together their clinical trials protocol. It contains both instructional and sample text and was harmonized with a protocol template for industry-sponsored research developed by Transcelerate Biopharma. Additionally, it meets standards set by the International Conference on Harmonization (ICH) E6 Good Clinical Practice guidelines. The e-protocol writing tool allows for:

- Collaboration between writers and reviewers as individuals can be assigned to different sections of the protocol
- Smooth workflow as email notifications send alerts as to when a section is ready for review
- Export of the final protocol document for submission for external review

So, how can this help you in your work?

- A standardized protocol format makes the protocol development process easier and more efficient
- Online collaboration between writers and reviewers allows for a smooth workflow
- A smoother, faster protocol development process means a quicker turnaround time between development and submission to regulators and review boards
- With the protocol having a standardized format and meeting industry standards, it increases the likelihood of your protocol being well organized and having all the necessary information that regulators and reviewers are looking for. This could increase the possibility of faster acceptance of your protocol
- Increased efficiencies save time and money

Remove the stress from clinical trial protocol development and ensure your protocols meet ICH E6 Good Clinical Practice Guidelines with the FDA-NIH e-protocol writing tool.

CANADIAN AFFAIRS

Medical Assistance in Dying Legislation passed in Ontario

Have you developed your policies to support Bill C-14?

On May 9, 2017, Ontario passed Bill 84, Medical Assistance in Dying Statute Law Amendment Act. This legislation supports Bill C-14 passed by the federal government in June 2016, and is meant to provide more protection and greater clarity for patients, their families, healthcare providers and health care institutions as they work around the matter of medical assistance in dying.

Bill C-14 outlines the requirements for patient eligibility for medical assistance in dying, and establishes safeguards for the legal provision of medical assistance in dying that doctors and nurse practitioners must abide by. The Medical Assistance in Dying Statute Law Amendment Act, deals with those areas from Bill C-14 that fall under provincial jurisdiction. Two (2) of the areas addressed are:

- Care providers, doctors, nurse practitioners and people assisting them, are protected against litigation for medical assistance in dying unless there is alleged negligence
- A doctor or nurse practitioner who provides medical assistance in dying, has to notify the coroner and provide any information that is needed to determine whether the death must be investigated, and other people with knowledge of the death shall provide the coroner with information on request

Medical assistance in dying is now the law. Take the first step in complying with the law by developing policies that are clearly defined in line with Bill C-14 and Bill 84. Ensure that these policies are well organized and easily accessible by all staff. Get additional information from the Ministry of Health and Long Term Care.

At PolicyMedical, we value you, our clients and love to hear from you. If you have any feedback on features and functionalities that you want to see in the software, or any input and suggestions for improvement, please leave them in the 'Feedback' section of the application.

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