

○ Unsafe conditions—circumstances that increase the probability of a patient safety event.

Common Formats Version 1.1 is currently limited to patient safety reporting for acute care hospitals and is designed to support the first stage in the improvement cycle. Version 1.1 includes two general types of formats, generic and event specific. The generic Common Formats pertain to all patient safety concerns. The three generic formats are: Healthcare Event Reporting Form, Patient Information Form, and Summary of Initial Report. The event-specific Common Formats pertain to frequently occurring and/or serious patient safety events. The eight event-specific formats are: Blood or Blood Product, Device or Medical/Surgical Supply, Fall, Healthcare-Associated Infection, Medication or Other Substance, Perinatal, Pressure Ulcer, and Surgery or Anesthesia.

As part of the Agency's efforts to continually refine and update the formats, AHRQ has issued a significant revision of the previously released Common Format—Device or Medical/Surgical Supply. In conjunction with the Food and Drug Administration (FDA) and the Office of the National Coordinator for Health Information Technology (ONC), AHRQ developed the beta version of this event-specific format to capture information about patient safety events that are related to HIT. Subsequently, the format was reviewed and revised by an interagency Federal Patient Safety Work Group (PSWG). The enhanced format, Device or Medical/Surgical Supply including HIT Device, will be incorporated into the next version of the Common Formats (Version 1.2).

This revised format includes a description of patient safety events and unsafe conditions to be reported (event description) and a sample patient safety aggregate report and individual event summary. The Device or Medical/Surgical Supply including HIT Device Common Format is available at the Patient Safety Organization (PSO) Privacy Protection Center (PPC) Web site: <https://www.psoppc.org/web/patientsafety>.

Commenting on Device or Medical/Surgical Supply Including HIT Device Common Format, Version 1.1

To allow for greater participation by the private sector in the subsequent development of the Common Formats, AHRQ engaged the National Quality Forum (NQF), a non-profit organization focused on health care quality, to solicit comments and advice to guide the further refinement of the Common

Formats. The NQF began this process with feedback on AHRQ's 0.1 Beta release of the Common Formats. Based upon the expert panel's feedback, AHRQ, in conjunction with the PSWG, further revised and refined the Common Formats and released Version 1.0.

The review process above was repeated again from September 2009 through February 2010 to further refine Common Formats Version 1.0 and incorporate public comments prior to finalization of the technical specifications for electronic implementation. These revised formats are now available as Version 1.1.

As evidenced by the release of this Device or Medical/Surgical Supply including HIT Device format, AHRQ is committed to continuing refinement of the Common Formats. The Agency is specifically interested in obtaining feedback from both the private and public sectors, particularly from those who use the Common Formats, to guide their improvement. Information on how to comment and provide feedback on the Common Formats, Version 1.1 and the Device or Medical/Surgical Supply including HIT Device beta version, is available at the National Quality Forum (NQF) Web site for Common Formats: <http://www.Quality.forum.org/projects/commonformats.aspx>.

Common Formats Development

In anticipation of the need for Common Formats, AHRQ began their development in 2005 by creating an inventory of functioning private and public sector patient safety reporting systems. This inventory provides an evidence base that informs construction of the Common Formats. The inventory now numbers 69 and includes many systems from the private sector, including prominent academic settings, hospital systems, and international reporting systems (e.g., from the United Kingdom and the Commonwealth of Australia). In addition, virtually all major Federal patient safety reporting systems are included, such as those from the Centers for Disease Control and Prevention (CDC), FDA, the Department of Defense (DOD), and the Department of Veterans Affairs (VA).

Since February 2005, AHRQ has coordinated the PSWG to assist AHRQ with developing and maintaining the Common Formats. The PSWG includes major health agencies within the HHS—CDC, Centers for Medicare & Medicaid Services, FDA, Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, the National Library of Medicine, ONC, the Office of Public Health and Science, the Substance

Abuse and Mental Health Services Administration—as well as the DoD and the VA.

The PSWG assists AHRQ with assuring the consistency of definitions/formats with those of relevant government agencies as refinement of the Common Formats continues. To the extent practicable, the Common Formats are also aligned with World Health Organization (WHO) concepts, framework, and definitions contained in their draft International Classification for Patient Safety (ICPS).

The process for updating and refining the formats will continue to be an iterative one. More information on the Common Formats Version 1.1 can be obtained through AHRQ's PSO Web site: <http://www.PSO.AHRQ.gov/index.html>.

Dated: October 12, 2010.

Carolyn M. Clancy,

Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2326-PN]

Medicare and Medicaid Programs; Application by the Joint Commission for Deeming Authority for Psychiatric Hospitals

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice with comment period acknowledges the receipt of an application from the Joint Commission for recognition as a national accrediting organization for psychiatric hospitals that wish to participate in the Medicare or Medicaid programs. Section 1865(a)(3)(A) of the Social Security Act requires that within 60 days of receipt of an organization's complete application, we publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 22, 2010.

ADDRESSES: In commenting, please refer to file code CMS-2326-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Submit electronic comments on CMS regulations with an open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2326-PN, P.O. Box 8010, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2326-PN, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the

SUPPLEMENTARY INFORMATION section.
FOR FURTHER INFORMATION CONTACT: L. Tyler Whitaker, (410) 786-5236. Patricia Chmielewski, (410) 786-6899.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed notice to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-2326-PN and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Electronic Comments on CMS Regulations" on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a psychiatric hospital provided certain requirements are met. Section 1861(f) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a psychiatric hospital. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 482, subpart E specify, among other things, the conditions that a psychiatric hospital must meet in order to participate in the Medicare program.

Generally, in order to enter into a provider agreement with the Medicare program, a psychiatric hospital must first be certified by a State survey agency as complying with the applicable conditions or requirements set forth in 42 CFR part 482. Thereafter, the psychiatric hospital is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. However, there is an alternative to surveys by State agencies.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for deeming authority under 42 CFR part 488, subpart A must provide us with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions of participation. The regulations at § 488.8(d)(3) require accrediting organizations to reapply for continued deeming authority every 6 years or sooner as determined by us.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.8(a) require that our findings concerning review and approval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and the ability to provide us with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of the Joint Commission's request for deeming authority for psychiatric hospitals. This notice also solicits public comment on whether the Joint Commission's requirements meet or exceed the

Medicare conditions for participation for psychiatric hospitals.

III. Evaluation of Deeming Authority Request

The Joint Commission submitted all the necessary materials to enable us to make a determination concerning its request for approval as a deeming organization for psychiatric hospitals. This application was determined to be complete on September 3, 2010. Under section 1865(a)(2) of the Act and § 488.8 (Federal review of accrediting organizations), our review and evaluation of the Joint Commission will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of the Joint Commission's standards for a psychiatric hospital as compared with CMS' psychiatric hospital conditions of participation.
- The Joint Commission's survey process to determine the following:
 - + The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.
 - + The comparability of the Joint Commission's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
 - + The Joint Commission's processes and procedures for monitoring psychiatric hospitals found out of compliance with the Joint Commission's program requirements. These monitoring procedures are used only when the Joint Commission identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency monitors corrections as specified at § 488.7(d).
 - + The Joint Commission's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.
 - + The Joint Commission's capacity to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.
 - + The adequacy of the Joint Commission's staff and other resources, and its financial viability.
 - + The Joint Commission's capacity to adequately fund required surveys.
 - + The Joint Commission's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.
 - + The Joint Commission's agreement to provide us with a copy of the most current accreditation survey together with any other information related to

the survey as we may require (including corrective action plans).

IV. Response to Public Comments and Notice Upon Completion of Evaluation

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget did not review this proposed notice.

In accordance with Executive Order 13132, we have determined that this proposed notice would not have a significant effect on the rights of States, local or Tribal governments.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773, Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 14, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0001]

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee

General Function of the Committee:

To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 1, 2010, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, Bldg 31, the Great Room, White Oak Conference Center (rm. 1503), 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You", click on "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings".

Contact Person: Nicole Vesely, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, e-mail: Nicole.vesely@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 301-451-2542. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On December 1, 2010, the committee will discuss supplemental new drug applications (sNDAs) 021-319/S-024, trade name AVODART (dutasteride) Soft Gelatin Capsules,