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CMS Updates


The Survey and Certification Group (SCG) is providing the third and final training program on the care of persons with dementia and unnecessary antipsychotic medication use. The first two programs were made available in January 2013; the third program will be released after May 31, 2013. The third program is a video-streaming that discusses how to cite severity. The first program provides survey basics related to care of persons with dementia and unnecessary medications. The second program is an interactive self-study with video clips that walks through portions of an actual nursing home survey. These three programs are mandatory for all State and Regional Office surveyors and optional for other interested personnel.

CMS Survey and Certification Letter 13-35: Advanced Copy: Dementia Care in Nursing Homes: Clarification to Appendix P State Operations Manual (SOM) and Appendix PP in the SOM for F309 - Quality of Care and F329 - Unnecessary Drugs (5/24/13)

This memo conveys clarification to Appendices P and PP related to nursing home residents with dementia and unnecessary drug use. Attached are the following:

SC 13-35-01-NH Partnership to Improve Care
SC 13-35-02-NH Attachment A: SOM Appendix P
SC 13-35-03-NH Attachment B: SOM Appendix PP
SC 13-35-04-NH Attachment C: Surveyor Checklist

CMS Survey and Certification Letter 13-36: Advance Copy- Changes for Sub-Task 5E, Medication
Pass Observation Protocol for Long Term Care (LTC) Facilities (6/7/13)

Changes have been made to Sub-Task 5E - Medication Pass Observation Task in the Traditional Survey: (1) The number of observations required to calculate the facility medication error rate is revised to a minimum of 25 medication administration opportunities. A minimum number is specified because it is acceptable to include more than 25 observations in a medication observation to capture multiple routes, times, and caregivers; (2) This revision eliminates the current requirement to extend the medication pass for another 20-25 opportunities if errors are detected in the first 20-25 observations; (3) Form CMS-20056 [CMS SC-13-36-03-NH Attachment B], Medication Administration Observation will be used; this form replaces Form CMS-677, Medication Pass Worksheet; and (4) This change matches the Quality Indicator Survey (QIS) Medication Administration Observation protocol, thus standardizing the medication error rate calculation for both the Traditional and QIS surveys. An advance copy of the revised SOM is provided [SC 13-36-02-NH Attachment A].


CMS is making the following set of introductory materials available on the CMS QAPI website:

- **QAPI at a Glance** - a guide for understanding and implementing QAPI in nursing homes
- **QAPI Tools** - process tools, within QAPI at a Glance, to help providers establish a foundation in QAPI
- **QAPI News Brief** - newsletter describing basic principles of QAPI
- **Video** - *Nursing Home QAPI - What's in it for you?* - introduces QAPI, its value to residents, their families and caregivers, and what is in it for nursing homes that embrace QAP

Analysis is nearly complete on wave one of the Nursing Home Quality Improvement Questionnaire; results will be released on QAPI Website later this summer. A new webpage to house QAPI training materials, tools and resources has been created on the CMS website at [http://go.cms.gov/Nhqapi](http://go.cms.gov/Nhqapi). CMS will expand its QAPI efforts by developing resources for consumers.

**Epidemiology Update**

The Centers for Disease Control and Prevention (CDC) recently released new guidance for the testing of hepatitis C. CDC issued this update in guidance because of 1) changes in the availability of certain commercial HCV antibody tests, 2) evidence that many persons who are identified as reactive by an HCV antibody test might not subsequently be evaluated to determine if they have current HCV, and 3) significant advances in the development of antiviral agents with improved efficacy against HCV.

Although previous guidance focused on strategies to detect and confirm HCV antibody, reactive results from HCV antibody testing cannot distinguish between persons whose past HCV infection has resolved and those who are currently HCV infected. Persons with current infection who are not identified as currently infected will not receive appropriate preventive services, clinical evaluation, and medical treatment. Testing strategies must ensure the identification of those persons with current HCV infection. A recent article describes testing for hepatitis C, including new technologies in testing, identifying current infection, benefits of testing, the new recommended testing sequence and more.

To read the full article click on the following link, [http://1.usa.gov/12oVQku](http://1.usa.gov/12oVQku).
Recalls and Advisories

Warfarin 2 mg Tablets by Zydus Pharmaceuticals USA Inc.: Recall - Due to Oversized Tablet

June 12, 2013

ISSUE: Zydus Pharmaceuticals USA Inc. is voluntarily recalling one lot of Warfarin 2 mg Tablets, Lot #MM5767, expiration date June 2014 to the retail level. Four tablets of Warfarin 2 mg Tablets, Lot MM5767, have been found to be oversized in one product complaint.

Ingestion of a greater than intended dose of Warfarin, could lead to an increased pharmacological effect of warfarin. As a result, patients would be more likely to develop bleeding as an adverse reaction and in some patients that bleeding into a critical organ (mostly the central nervous system) could be fatal. The risk of bleeding is increased if overdosing is repeated continuously on a daily basis.

BACKGROUND: The product is used as prophylaxis and treatment of venous thrombosis and its extension, pulmonary embolism (PE), prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation (AF) and/or cardiac valve replacement and reduction in the risk of death, recurrent myocardial infarction (MI), and thromboembolic events such as stroke or systemic embolization after myocardial infarction. Product is packaged in HDPE Bottle of 1000's count, which may have been dispensed to patients in smaller bottles. The only lot affected of Warfarin 2 mg Tablets being recalled is Lot MM5767.

The product can be identified by its NDC #6838205310. The product was distributed nationwide in the United States to wholesalers/distributors, retailers and mail order providers, from November 2012 to December 2012.

RECOMMENDATION: Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this particular lot of Warfarin 2 mg Tablets. Anyone with an existing inventory of this particular Lot MM5767 of Warfarin 2 mg Tablets should stop use and distribution, quarantine the recalled lots immediately and call INMAR at 1-800-967-5952 between the hours of 7 a.m. to 4 p.m. CST, Monday through Friday, to arrange for their return. In case patients have tablets of this lot of product, make sure all the tablets are of same size and if unsure, patients should consult their dispensing pharmacy.