

AHCA SPECIFIC COMMENTS ON THE EPA'S DRAFT QUESTIONNAIRE FOR UNUSED PHARMACEUTICALS DISPOSAL IN THE HEALTH SERVICES INDUSTRY

INSTRUCTION FOR COMPLETING THE QUESTIONNAIRE

Instructions

Bullet 2

- The instruction to not skip questions when answers cannot be found will lead to guesses and invalid responses. We recommend simplifying the questionnaire so that the information requested is achievable and can be obtained by LTC providers with a reasonable amount of time.

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- Bullet 2: We do not understand the rationale for noting the number of copies/pages when photocopying is needed. Rewrite the sentence to improve clarity.
- Bullet 4: Instructions should identify that any facility involved in disaster (hurricane, fire, etc.) relief (taking in patients) and discharge (sending out patients), and those facilities acquired or sold during the period of survey call the EPA to withdraw from the survey. In these situations, facilities will be unable to obtain and or accurately obtain the requested data for the survey.
- Bullet 5: Monthly drug disposal data is not information routinely collected by LTC facilities.

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- **CONFIDENTIAL BUSINESS INFORMATION:** LTC facilities do not have the personnel to fully respond to all the questions posed in the survey and complete the request to keep information confidential. Since financial information is requested as well as facility policy information, we recommend that all survey responses be considered confidential.

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- **CERTIFICATION STATEMENT:** The statement specifies that “qualified personnel” gather the survey information. LTC facilities do not employ individuals with the expertise needed to accurately and validly answer all the questions. Since the questionnaire instructions do not allow questions to be left unanswered, the statement forces LTC personnel to certify the accuracy of questionable information. If EPA implements the proposed survey, we recommend eliminating the certification statement.

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- **PART A: FACILITY INFORMATION:** A4 suggests the head pharmacist, director of nursing or the medical director complete the survey. Most LTC facilities do not have in-house pharmacy and medical director. Considering this, the survey responsibility will fall on the director of nursing. As mentioned in the general and above Certification Statement comments, the LTC structure does not provide the needed experts to complete the questionnaire. We recommend that EPA reconsider the use of the questionnaire in the LTC setting and work with industry representative on an alternative information gathering approach if required.

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- A6: The identified selection options for LTC do not correlate with the definition found on D-2. In addition, Continuing Care/Retirement Communities (CCRCs) have several different settings. It is not clear if all or part of CCRCs are required to complete the information. Clarification is needed.
- A10: Many LTC facilities deal with several pharmacies. For example, the facilities may receive prescription medications from one pharmacy, stock drugs from another, and Hospice may request use of their own pharmacy. Thus, the question needs to acknowledge the plural.

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- A11: Consider adding a response option “All that Applies.”
- Table A-1 uses the descriptor “facility.” Again, please clarify how CCRCs are to respond to questions using “facility.”
- A12: LTC facilities will be unable to accurately attain and accurately provide the requested information. The questionnaire does not offer any standards for measurement. For example, are oral liquids to be reports in ccs, tsps, drams, etc? Do facilities subtract the number of ccs remaining in the bag when the IV is discontinued? How do facilities report the amount of creams/ointments that it has not used? We recommend that EPA set measurement standards.

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- A13: Once again the need for measurement standards is needed. It is also not clear if stock drugs and those given by hospice are considered for response in this question.
- A14: It is not clear why EPA needs to know why drugs are not used and how this information relates to pharmaceuticals in ground water.

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- A16: The survey needs to define “Hazardous Waste.” Hazardous waste can mean biological wastes and chemical waste that may be used by maintenance personnel.
- None of the question options pertain to LTC.
- Pyxis are cost-prohibitive and are minimally used in LTC. Where they are used, the Pyxis is used solely for controlled substances. For example, in New York State LTC facilities use Pyxis only for controlled substances since State law requires facilities to have a particular pharmacy license that allows storage and dispensing of all drugs from the Pyxis. The pharmacy license criteria is difficult for a stand-alone LTC facility to meet without having an onsite pharmacy.
- A17: Again, hazardous waste needs to be defined.

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- A18: Instead of Table A-2, we recommend that EPA use the AHCA state survey.

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- A21: LTC facilities do not keep monthly records of disposed unused pharmaceuticals. Again, need to define hazardous waste.

Page A-9

- A22: There is no national Medicare policy related to drug disposal. We are also not aware of any state Medicaid rules specifically governing the disposal of unused pharmaceuticals. Consider removing Medicare option from question responses.

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- A26: The question responses need to include whether the facility gives the unused portion of prescribed drugs/ointment/creams to patients on discharge from the facility.

Page A-12

- A28: What is meant by “Cost Reduction?”

Page B-1

- B1: It is not clear why the number of part-time and full-time employee information is required and is needed. Collecting employee information is more complicated than providing head counts. For example, many health care facilities use contract labor like care givers, and in some facilities, entire departments like housekeeping are contracted. In addition, LTC facilities use volunteers on a regular basis and other contractor like therapists and hospice.
- B2 through B4: We recommend that the entire B Section that not be used for LTC since EPA can obtain the information via other public records that facilities are required to file annually and pertain to revenues, operating costs and ownership.

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- COMMENTS: The data collection tool is cumbersome and complex. We have already recommended that EPA omit facilities from the survey who have either admitted or discharge patients due to a natural disaster or fire and who have been sold or bought during the period of information request.

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- DEFINITIONS: Need to define “facility” as it relates to CCRCs; “long term care” for inclusion or exclusion of facility-based hospice services versus contracted services; and “hazardous waste.” In addition, many LTC facilities refer to the post acute care (short-stay) population as “patients.” The current definition for patient only specifies those receiving care in hospitals.

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- POLLUTION PREVENTION: As indicated in our general comments, reducing the amount of unused pharmaceuticals in LTC facilities will have little impact on pollution prevention since the amount of prescription, over-the-counter drugs, and herbals use is greater in community-dwelling elders.