

Q181: Administration of Drugs

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As part of the Bureau of Facility Standards ASC Quality Improvement Initiative, ASC QAPI regulations (Q80 – Q84) were applied to statewide quality indicator data. The quality indicator data, which included complaints alleging non-compliance with ASC regulatory requirements, provider questions regarding regulatory requirements, and citation data from 2009 through 2013, was reviewed and analyzed. Based on that analysis, it was determined additional training regarding Administration of Drugs (Q181) would be beneficial in improving regulatory understanding and compliance. For additional information regarding the statewide quality indicator data and analysis, please refer to the Applied QAPI: Statewide ASC Quality Improvement Initiative training on the BFS web site.

<http://healthandwelfare.idaho.gov/Portals/0/Medical/LicensingCertification/ASCAppliedQAPI%20.pdf>

Learning Goals

- Identify the 11 specific areas within medication administration which frequently result in citations.
- Identify the 5 specific areas which represent 73% of all Q181 citations.
- Describe how citation information can be incorporated into an ASC QAPI program.
- Describe the QAPI and Governing Body implications for repeat citations.

Appendix L

- The regulation at Q181, Administration of Drugs, states “Drugs must be prepared and administered according to established policies and acceptable standards of practice.”

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The regulation at Q181 is wide reaching and includes all areas of medication preparation and administration as stated in the interpretive guidance:

“Drugs and biologicals used within the ASC must be administered to patients in accordance with formal policies the ASC has adopted, and those policies and the ASC's actual practices must conform to acceptable standards of practice for medication administration.

‘Accepted professional practice’ and ‘acceptable standards of practice’ mean that drugs and biologicals are handled and provided in the ASC in accordance with applicable State and Federal laws as well as with standards established by organizations with nationally recognized expertise in the clinical use of drugs and biologicals. This would include organizations such as the National Association of Boards of Pharmacy, the Institute for Safe Medication Practices, the American Society of Health-System Pharmacists, etc.

The ASC must have policies and procedures designed to promote medication administration consistent with acceptable standards of practice. The policies and procedures should address issues including, but not limited to:

- o A physician or other qualified member of the medical staff acting within their scope of practice must issue an order for all drugs or biologicals administered in the ASC. The administration of the drugs or biologicals must be by, or under the supervision of, nursing or other personnel in accordance with applicable laws, standards of practice and the ASC's policies.

- o Following the manufacturer's label, including storing drugs and biologicals as directed; disposing of expired medications in a timely manner; using single-dose vials of medication for one ASC patient only; etc.

- o Avoiding preparation of medications too far in advance of their use. For example, while it may appear efficient to pre-draw the evening before all medications that will be used for surgeries scheduled the following day, this practice may, depending on the particular drug or biological, promote loss of integrity, stability or security of the medication.

- o Any pre-filled syringes must be initialed by the person who draws it, dated and timed to indicate when they were drawn, and labeled as to both content and expiration date.

- o Employing standard infection control practices when using injectable medications.

There must be records of receipt and disposition of all drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970, if the ASC uses any such scheduled drugs. The ASC's policies and procedures should also address the following:

- o Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs.

- o Records of the receipt and disposition of all scheduled drugs must be current and must be accurate.

- o Records to trace the movement of scheduled drugs throughout the ASC.

- o The licensed health care professional who has been designated responsible for the ASC's pharmaceutical services is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled.

o The record system, delineated in policies and procedures, tracks movement of all scheduled drugs from the point of entry into the ASC to the point of departure, either through administration to the patient, destruction, or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

o All drug records are in order and an account of all scheduled drugs is maintained and any discrepancies in count are reconciled promptly.

o The ASC's system is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.”

Performance Improvement Projects

	2009	2010	2011	2012	2013	Totals
Expired medications	0	8	4	2	3	17
Multi-dose vials not labeled with open date	0	5	2	0	3	10
Improper labeling of pre-drawn syringes	2	3	1	1	1	8
Single use vials used for multiple patients	0	0	1	1	4	6
No read back and verify of verbal orders	2	2	1	0	0	5
No orders for medications given	0	1	1	1	1	4
Medications not secure	1	0	1	0	2	4
No control count for narcotics	0	1	0	1	2	4
No log for receipt and disposition of meds.	1	1	0	1	0	3
Incomplete orders (dose not identified)	0	0	0	1	0	1
Medications improperly stored	0	0	0	0	1	1

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However, when quality indicator data was analyzed, it was determined that of all the areas related to drug preparation and administration there are 11 specific areas that are being cited (as indicated on the slide). Additionally, of those 11 areas, there are only 5 areas which represent 73% of all Q181 citations. These are:

Number 1: Expired medications.

Number 2: Multi-does vials not being labeled with an open date.

Number 3: Improper labeling of pre-drawn syringes.

Number 4: Single use vials being used for multiple patients.

Number 5: No read back and verification of verbal orders.

Number 1: Expired Medications

- Medication and biologicals must be regularly monitored and removed when they expire.

Governing Body questions:

- How does your ASC monitor medication expiration?
- Has quality indicator data for expired medications been collected and analyzed as part of your ASC's QAPI program?

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Q181 interpretive guidance states “Following the manufacturer's label, including storing drugs and biologicals as directed; disposing of expired medications in a timely manner; using single-dose vials of medication for one ASC patient only; etc.”

The number one reason for Q181 citations is expired medications being in circulation for patient use. Please be aware, during the survey process all medications, including medications in emergency carts will be observed and dates will be checked to ensure they are not expired.

When looking at your ASC's medication systems, has the Governing Body developed policies and procedures to ensure expired medications and biologicals are removed? How is the Governing Body monitoring to ensure the policies and procedures are being implemented appropriately? Is the discovery of expired medications included in QAPI quality indicator data collection? Has the data been analyzed? If after analysis, if a problem exists, what action did the Governing Body take to improve the process for removing expired medications from patient use? Has there been continued data collection and analysis to ensure the problem was resolved and does not reoccur?

Number 2: Labeling Multi-dose Vials

- Multi-dose vials must be labeled with an open date.

Governing Body questions:

- How does your ASC label multi-dose vials? How does your ASC ensure multi-dose vials are discarded when the 28th day is reached?
- Has quality indicator data for multi-dose vial labeling and 28 day discard been collected and analyzed as part of your ASC's QAPI program?

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The number 2 reason for Q181 citations is also related to expired medications. United States Pharmacopeia (USP) 797: Guidebook to Pharmaceutical Compounding - Sterile Preparations, Second Edition, 6/01/08, states if a multi-dose vial has been opened or accessed, the vial should be dated and discarded within 28 days unless the manufacturer specifies a different date for that opened vial.

If the facility is using multi-dose vials, the vials have to be labeled with an open date in order to know when the 28 day expiration date is reached. Without knowing when the vial was opened, the ASC cannot ensure the medication has not expired.

Again, please be aware, during the survey process all medications, including multi-dose vials, will be observed to ensure they are appropriately labeled and have not surpassed the 28 day period.

When looking at the ASC's medication systems, the same Governing Body and QAPI questions are asked: has the Governing Body developed policies and procedures to ensure multi-dose vials are labeled with an open date and are removed when the 28th day is reached? How is the Governing Body monitoring to ensure the policies and procedures are being implemented appropriately? Is the discovery of inappropriately labeled or expired (past the 28th day) multi-dose vials included in QAPI quality indicator data collection? Has the data been analyzed? If

after analysis, it was determined a problem exists, what action did the Governing Body take to improve the ASC's process for ensuring multi-dose vials are labeled and removed at 28 days? Has there been continued data collection and analysis to ensure the problem was resolved and does not reoccur?

Number 3: Labeling Pre-drawn Syringes

- Pre-drawn syringes must be initialed by the person who draws them, dated and timed to indicate when they were drawn, and labeled as to both content and expiration date.

Governing Body questions:

- How does your ASC label pre-drawn syringes?
- Has quality indicator data for labeling of pre-drawn syringes been collected and analyzed as part of your ASC's QAPI program?

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The number 3 reason for Q181 citations is also related to labeling. The Q181 interpretive guidance states "Any pre-filled syringes must be initialed by the person who draws it, dated and timed to indicate when they were drawn, and labeled as to both content and expiration date."

Again, please be aware, during the survey process any pre-drawn syringes will be observed to ensure they are appropriately labeled.

When looking at your medication systems, the same Governing Body and QAPI questions are asked (as stated in the notes section of slides 5 and 6) as they pertain to the labeling of pre-drawn syringes.

Number 4: Single Use Vials

- Single-use vials of medication can only be used for a single patient.

Governing Body questions:

- How does your ASC use single-use vials?
- Has quality indicator data for single-use vials been collected and analyzed as part of your ASC's QAPI program?

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The number 4 reason for Q181 citations is related to vials marked as single patient use. The Q181 interpretive guidance states the ASC must always be “Following the manufacturer's label, including storing drugs and biologicals as directed; disposing of expired medications in a timely manner; using single-dose vials of medication for one ASC patient only; etc.”

During the survey process, surveyors have observed a vial of medication being drawn into several different syringes, with a new syringe being used for each entry into the vial. Each syringe is then used for a single patient. This practice is acceptable for multi-dose vials. However, when the vial is labeled for single patient use, the medication within the vial cannot be used for multiple patients.

Facilities will typically implement the practice of using a single patient vial for multiple patients in an effort to not waste medications. It has been reported that certain medications only come in single patient vials, but a single patient does not need all of the medication in the vial. Therefore, in an effort to not waste the remaining medication, facilities will continue using the single patient vial for other patients until it is gone. This is **not** an acceptable practice.

Again, when looking at your ASC's medication systems, the same Governing Body and QAPI questions are asked (as stated in the notes section of slides 5 and 6) as

they pertain to single-use vials.

Number 5: Read Back and Verify

- Orders obtained verbally must be:
 - Read back to the physician
 - Verified by the physician
 - Followed-up with obtaining the physician's signature (with date and time) as soon as possible

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The number 5 reason for Q181 citations is related to read back and verification of verbal orders. The interpretive guidance at Q181 states "Orders for drugs and biologicals that are transmitted as oral, spoken communications between the prescribing physician and the ASC's nursing staff, delivered either face-to-face or via telephone, commonly called 'verbal orders,' must be followed by a written order that is signed by the prescribing physician.

CMS expects ASC policies and procedures for verbal orders to include a read-back and verification process whereby the nurse receiving the order repeats it back to the prescribing physician, who verifies that it is correct. When administering a drug or biological per a verbal order, the nurse should include in the medical record entry covering the administration of the drug or biological a note that it was prescribed orally, indicating the name of the prescribing physician.

The prescribing physician must sign, date, and time the written order in the patient's medical record confirming the verbal order. This should be done as soon as possible after the verbal order is issued.

In the ASC setting medications prescribed for patients in recovery present a particular area of vulnerability in terms of the potential failure to follow-up a verbal order with a written order signed by the prescribing physician. Careful attention

must be given to compliance with the regulatory requirement for medications administered during recovery room.”

Number 5: Read Back and Verify

Governing Body questions:

- How does your ASC handle verbal orders?
- Has quality indicator data for verbal orders been collected and analyzed as part of your ASC's QAPI program?

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Please be aware that during the survey process, surveyors will observe at least one procedure, following the patient from admission to discharge. During that time, surveyors will make note of any verbal orders given. Failure to ensure the order is read back and verified will result in citation.

Again, when looking at your medication systems, the same Governing Body and QAPI questions are asked (as stated in the notes section of slides 5 and 6) as they pertain to verbal orders.

By now you have probably noticed a pattern. All deficient practices should be evaluated by the Governing Body and incorporated into your QAPI program. Those same principles apply to all regulations.

Numbers 6 & 10: Orders for Medications

- Physician's orders (including patient name, medication name, route, dose, and time) must be obtained prior to administering any medication.

Governing Body questions:

- How does your ASC ensure medication orders are obtained and documented?
- Has quality indicator data for medication orders and documentation been collected and analyzed as part of your ASC's QAPI program?

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The number 6 reason for Q181 citations is related to physician orders for medications. The interpretive guidance at Q181 states "A physician or other qualified member of the medical staff acting within their scope of practice must issue an order for all drugs or biologicals administered in the ASC. The administration of the drugs or biologicals must be by, or under the supervision of, nursing or other personnel in accordance with applicable laws, standards of practice and the ASC's policies."

Please be aware during the survey, surveyors will observe a patient's procedure and complete record reviews. If medication administration is observed or if the patients' medical records document medications were given, then corresponding physicians' orders must be present. The documentation of physician orders must also be complete. Failure to ensure complete documentation is the number 10 reason why Q181 is cited. It should also be noted that documentation deficiencies may also be cited at Q162 for form and content of records.

Again, when looking at your medication systems, the same Governing Body and QAPI questions are asked (as stated in the notes section of slides 5, 6, and 11) as they pertain to medication orders and documentation. Has the Governing Body developed policies and procedures to ensure medication orders are obtained prior to administration and appropriately documented? How is the Governing Body

monitoring to ensure the policies and procedures are being implemented appropriately? Is the discovery of a lack of orders and/or documentation included in QAPI quality indicator data collection? Has the data been analyzed? If after analysis, it was determined a problem exists, what action did the Governing Body take to improve the ASC's process for ensuring medications are appropriately ordered and documented? Has their been continued data collection and analysis to ensure the problem was resolved and does not reoccur?

Numbers 7 & 11: Medication Storage - Security

- Medications must be stored in a secure location where only authorized persons have access.
- The above also applies when the medication is in use. For example, if a bottle of liquid medication used for multiple patients is being transported from room to room, the medication must have a lid and remain under the control of an authorized person.

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The number 7 reason for Q181 citations is related to medication storage systems. Number 7 is specifically related to drugs not being secured. The interpretive guidance at Q181 states the ASC must always be “Following the manufacturer’s label, including storing drugs and biologicals as directed...”

Please be aware during the survey, surveyors will observe patient care and the environment, including all drug storage areas, assessing for medication security. ASC providers have asked specific questions related to “double locking” of controlled substances (**please refer to the ASC Frequently Asked Questions posted on the BFS web site for a full listing of all provider questions:**

<http://healthandwelfare.idaho.gov/Portals/0/Medical/LicensingCertification/ASCFAQs.pdf>).

The ASC regulations at Q180 (Condition) and Q181 (standard) requires drugs and biologicals to be stored in a safe manner. When determining effective controls and procedures to prevent against diversion of controlled substances, the Idaho Board of Pharmacy and the DEA both use any or all of the security requirements set forth in 21 CFR §1301.72-1301.76.

21 CFR §1301.75(b) states that controlled substances in Schedules II-V shall be

stored in a securely locked, substantially constructed cabinet. There is no specific requirement that mandates a “double lock & key.” However, access of controlled substances is to be restricted to a minimum number of authorized individuals. Recognizing that unauthorized individuals may need to access locked medication rooms, nurses' stations, or other drug storage room locations, it is logical to further restrict the controlled substances within the drug storage room; thus the “double lock and key” expression.

Additionally, while not specifically related to the survey process, there have been recent reports of health care facilities being broken into and held up at gun point by individuals looking to steal narcotic medications.

Numbers 7 & 11: Medication Storage – Infection Control

- Medications must be stored in accordance with instructions on the label (e.g. refrigerated).
- The above still applies when the medication is in use. For example, if a bottle of liquid medication used for multiple patients is being transported from room to room, the medication must have a lid and remain in the possession of an authorized person.

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The number 11 reason for Q181 citations is also related to medication storage systems. Where number 7 is specifically related to drugs not being secured, number 11 is related to pre-drawn syringes not being stored in a location to prevent cross-contamination.

Again, please be aware during the survey, surveyors will observe patient care and the environment including all drug storage areas, assessing for infection control. CMS has developed an ASC Infection Control Surveyor Worksheet (Exhibit 351). This worksheet is completed during all surveys and includes infection control practices related to medications. Please refer to the Worksheet for additional comprehensive information:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf

Number 7 & 11: Medication Storage

Governing Body questions:

- How does your ASC ensure medications are appropriately stored in a safe and secure manner?
- Has quality indicator data for the safety and security aspects of medication storage been collected and analyzed as part of your ASC's QAPI program?

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Again, when looking at your medication systems, the same Governing Body and QAPI questions are asked (as stated in the notes section of slides 5, 6, and 11) as they pertain to medication storage.

Numbers 8 & 9: Medication Tracking

- Narcotic medications must be tracked at the time they arrive at the facility.
- A log of the number of narcotic medications must be maintained until the time they are disposed of or administered.

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The number 8 and number 9 reasons for Q181 citations is related to medication tracking systems. The interpretive guidance at Q181 states “There must be records of receipt and disposition of all drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970, if the ASC uses any such scheduled drugs.

o Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs.

o Records of the receipt and disposition of all scheduled drugs must be current and must be accurate.

o Records to trace the movement of scheduled drugs throughout the ASC.

o The licensed health care professional who has been designated responsible for the ASC's pharmaceutical services is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled.

o The record system, delineated in policies and procedures, tracks movement of all

scheduled drugs from the point of entry into the ASC to the point of departure, either through administration to the patient, destruction, or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

- o All drug records are in order and an account of all scheduled drugs is maintained and any discrepancies in count are reconciled promptly.

- o The ASC's system is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.”

Please note drugs must also be disposed of properly. For comprehensive information related to drug disposal, please refer to the FDA and DEA websites:

FDA

<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm>

DEA

http://www.deadiversion.usdoj.gov/drug_disposal/index.html

Numbers 8 & 9: Medication Tracking

Governing Body questions:

- How does your ASC ensure medications are appropriately tracked?
- Has quality indicator data for the medication tracking been collected and analyzed as part of your ASC's QAPI program?

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Again, when looking at your medication systems, the same Governing Body and QAPI questions are asked (as stated in the notes section of slides 5, 6, and 11) as they pertain to medication tracking.

Plans of Correction & QAPI

- Plans of Correction require ASCs to include information regarding how the deficient practice corrections will be monitored and tracked to ensure the PoC is effective in bringing the ASC into compliance, and that the ASC remains in compliance with the regulatory requirements.
- Repeat deficiencies.

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Whenever an ASC is cited for a deficient practice, the ASC is required to submit a Plan of Correction (PoC). For additional comprehensive information related to PoCs, please refer to the PowerPoint presentation Understanding the 2567 & Writing Acceptable Plans of Correction For Ambulatory Surgical Centers on the BFS website.

http://healthandwelfare.idaho.gov/Portals/0/Medical/LicensingCertification/ASC2567_AcceptPoCs.pdf

Part of the PoC requirements include monitoring and tracking to ensure the PoC is effective in bringing the ASC into compliance, and that the ASC remains in compliance with the regulatory requirements. Throughout this presentation, it has been demonstrated how each deficient practice should be assessed and monitored through the ASC's QAPI program.

Please be aware that surveyors review past survey reports and your PoC prior to conducting the next survey. When repeat deficiencies are identified (deficiencies which were cited during the last survey and are being cited again during the current survey) it calls into question your QAPI program and the Governing Body's ability to achieve and sustain compliance over time. Repeated deficiencies can result in Condition level findings at both QAPI (Q80) and Governing Body (Q40).

QAPI & Governing Body

- Survey results should not be a surprise. If the QAPI system is comprehensive in accordance with regulations Q80 – Q84, the facility will have identified areas in need of improvement (i.e. deficient practices) prior to a survey being conducted.

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While this presentation focused on how deficient practices with Q181 could be addressed within an ASC's QAPI program, it should be noted a comprehensive, well designed, implemented and monitored QAPI program allows the facility to identify areas in need of improvement prior to a survey occurring.

Ultimately this is the responsibility of the Governing Body. The regulation and interpretive guidance at Q84 states "The governing body must ensure that the QAPI program-

- (1) Is defined, implemented, and maintained by the ASC.
- (2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness.
- (3) Specifies data collection methods, frequency, and details.
- (4) Clearly establishes its expectations for safety.
- (5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.

An ongoing, successful QAPI program requires the support and direction of the ASC's leadership. This regulation makes clear CMS' expectations that the ASC's governing body must assume responsibility for all aspects of the design and and [sic] implementation of every phase of the QAPI program..."

Please ensure your QAPI program is implemented and maintained not only to meet the minimum regulatory requirements, but to ensure your patients are receiving the highest quality of care possible.

Questions

- Please submit your questions, comments or suggestions to fsb@dhw.idaho.gov

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Should you have questions, comments or suggestions regarding this or other aspects of the ASC survey process, please submit them to the Facility Standards email.