

As President of the North Carolina Society for Respiratory Care, I have received many questions related to the hospital standard that requires medications to be delivered within 30 minutes before or after the scheduled due time. I hope the following information will be a benefit to our membership.

Clarification Regarding Administration of Inhaled Medications

Background

Last year, the North Carolina State Society notified AARC about a problem with the survey of hospitals in North Carolina. The issue involved surveyors citing a facility for failing to administer inhaled medications within the standard administration schedule (30-minute rule) even though the hospital had a written policy that permitted an extension of the timeframe.

The AARC was quick to do an informal survey of respiratory therapists across the country with respect to their hospitals' policies and learned that the majority of those who responded had a written policy that permitted the delivery of inhaled medications up to 60 minutes before or after the scheduled due time. Subsequently, the AARC laid out the issues in a formal written paper to CMS, emphasizing that the 60-minute schedule was a generally accepted standard for the profession. After discussing the issue verbally with CMS staff, it was suggested that AARC develop a formal position statement.

The AARC issue paper presents a comprehensive argument as to why inhaled medications administered by respiratory therapists are delivered in a time frame that is often different from a hospital's standard administration schedule. A copy of the paper is attached for your information and background.

AARC Position Statement

The AARC position statement was approved by its Board of Directors and endorsed by its Board of Medical Advisors (BOMA), which is comprised of physicians from national medical societies and organizations such as the American College of Chest Physicians, the American Thoracic Society, and the American Society of Critical Care Medicine, among others. A copy of the AARC position statement and the list of BOMA organizations are also attached.

The statement stresses the need for facilities to establish written policies for the safe and timely administration of inhaled medications that are appropriate for the individual facility and approved by the medical staff. The policies may differ from the standard medication schedules and time frames, but they may not exceed 60 minutes before or after the scheduled medication delivery due time for medications prescribed at an interval greater than or equal to four hours.

Action by Centers for Medicare and Medicaid Services (CMS)

Last November, CMS had a conference call with its regional survey and certification staff responsible for the oversight of state surveyors. CMS indicated on the call that it found the AARC's position to be an acceptable standard of practice by a nationally recognized organization for the delivery of inhaled medications by respiratory therapists. A copy of the position statement and a list of the BOMA organizations were provided to regional staff who in turn informed state surveyors during their monthly conference calls of CMS' acceptance of the standard.

Problems May Still Exist

We have heard from folks who say that their hospital wants to see something in writing from CMS. Unfortunately, this will not happen. If CMS had to write an instruction every time a nationally recognized organization developed a standard of practice, it would become an administrative burden. As a reminder, the hospital conditions of participation and state survey interpretive guidelines both refer to meeting the needs of patients "in accordance with acceptable standards of practice."

Some hospitals may continue to have problems. Remember though, first and foremost, the conditions require a hospital to have a sufficient number of respiratory therapists to carry out their responsibilities and medications must always be administered in compliance with the physician's order. Using the extended delivery time of up to 60 minutes cannot be viewed as a way to accommodate inefficiencies in the hospital.

If your hospital is experiencing problems with the survey and certification process, you should work to correct it at the local level by contacting the CMS Atlanta Regional Office for help. The Division of Survey and Certification Operations is listed in the following link:

<http://www.cms.hhs.gov/RegionalOffices/Downloads/AtlantaRegionalOffice.pdf>

If the regional office survey and certification person is unfamiliar with the issue or has problems with the AARC's position statement regarding administration of inhaled medications, let the NCSRC know. We will in turn contact the AARC for direction and they can follow-up with CMS central office staff for further advice and/or resolution as necessary.

Your Membership is Important

The North Carolina Society for Respiratory Care was a leader in this issue. The Society would like to thank the Managers Group and former President Bill Kiger, as well as many other respiratory therapists across our state. The collaboration with the AARC and its support of our concerns shows why your membership is so important to improve patient care.

Medication Delivery Standards – 30-Minute Window

The Issue

The American Association for Respiratory Care (AARC) has recently been made aware that State surveyors in North Carolina have cited a couple of hospitals for noncompliance with the hospital standards that govern medication administration (§482.23(c)(1)). This policy requires a hospital to ensure that drugs are administered, among other things, “in accordance with the approved medical staff policies and procedures.”

CMS survey procedures require surveyors to verify that written policies are being followed. In doing so, one of the things they look at is whether drugs are administered within 30 minutes before or after the scheduled time for administration. Some hospitals in the State have established written policies approved by its medical staff specific to the administration of respiratory therapy inhalation medications that have been in place for some time. These policies permit delivery of such medications within 1 hour before or after the scheduled due time.

We understand that some North Carolina surveyors have ignored these policies because they do not adhere to the “30-minute window” and are considered not to be administered as ordered by the physician, even if the order includes a statement “per RT protocol.” We would note that one NC hospital was cited because its policy for delivery of respiratory medications was 2 hours before or after the due time, which we deem to be beyond acceptable practice standards.

Until the recent surveys in North Carolina, the AARC has not been aware that this is a problem in other parts of the country and question if it is an isolated incident just in that state. We believe the recent de-certification and closing of the State’s Haywood Hospital may have contributed to the stepped-up review and are concerned that other hospitals that have developed RT medication policies in the State could be cited for noncompliance if this issue is not resolved. AARC is also concerned that problems could be encountered elsewhere.

We have discussed the problem with CMS’ lead analyst for survey and certification. One solution discussed was to encourage physician’s to change the way they write orders to ensure the order is “per RT protocols” and for hospitals to develop separate respiratory therapy policies for individual inhalation medications and dosages. We do not consider these actions to be a feasible approach to solving the issue. The AARC believes the simpler solution is to permit hospitals to establish written respiratory therapy policies that extend the current standard administration “before and after times” by an additional 30 minutes. Many hospitals across the country already have such policies in place.

Request to CMS

Hospitals throughout the country have developed specific written policies approved by their medical staff for the delivery of respiratory therapy medications that considers them to be on time if they are delivered within 1 hour before or after the scheduled administration. The AARC wants assurances from CMS that we can pass on to our membership that such policies are acceptable to state surveyors as long as the respiratory staff and hospital adhere to such policies.

Summary Analysis

In reviewing current policies and standards (see **Attachment 1**), the AARC believes that the conditions of participation permit hospitals to have the flexibility to develop written respiratory therapy medication administration procedures, based on generally accepted practices that differ from the standard administration times for non-inhalation drugs. The Joint Commission's policy also gives hospitals this flexibility under its medication management policies.

The policy of administering respiratory therapy medications 1 hour before or after the scheduled due time is a generally accepted standard that is evidenced by numerous hospital policies that have been established across the country. We are aware that other state surveyors have found this interpretation acceptable, and even the Kansas City Regional Office Survey, Certification and Enforcement Branch concurs.

In North Carolina, the current problem is not with the physician's order, but with the standardized times for delivery based on such orders. Despite hospital policy that permits delivery of inhalation drugs to be extended an additional 30 minutes before and after the scheduled time, respiratory therapists are being held to the same standard administration times as nurses who deliver non-inhalation medications. If a physician writes an order for an inhalation medication to be delivered 4 times a day QID and the hospital has a written policy that permits an exception to the standardized QID times for inhalation drugs, the delivery time should be acceptable within the interpretive guidelines because the patient is still receiving the medication 4 times a day as ordered by the physician.

Inhalation medications are delivered differently and take longer to administer than other non-inhalation drug. Respiratory therapists administer medications to patients who are spread throughout the facility (not in one concentrated area) which requires additional travel time to reach the patient. In addition, aerosolized medications administered during treatments have potential adverse reactions. Recognition of these reactions is not possible if the patient is left unattended, thus requiring additional time for the respiratory therapy to monitor the situation in order to avoid a safety hazard.

The AARC supports hospital efficiency and the delivery of quality care to ensure patient safety. We recognize that patient safety issues are in the forefront of these policies, however, scientific evidence suggests that a medication error does not occur until it is administered more than 60 minutes before or after the scheduled due time. In evaluating new health care systems that can reduce medication errors, one study even suggested that respiratory therapists had difficulty adhering to their hospital network's 1 hour "before and after" scheduled due time and recommended implementing staggered administration schedules or different schedules from the standard protocols as a way to alleviate unnecessary early- or late-dose errors.

Where hospitals choose to develop separate written policies regarding the delivery of respiratory therapy medications, the AARC is asking that delivery schedules for these inhalation medications that differ from the pharmacy standardized times by an additional 30 minutes be considered appropriate. In other words, we are asking for a larger window of time (i.e., 60 minutes before and after) for the delivery of inhalation medications based on the generally accepted standard for the profession.

If hospital policies that have been approved by the medical staff currently permit respiratory therapists to deliver medications 1 hour before or after the scheduled delivery time, then this should be acceptable to CMS and the surveyors. This is the simple solution.

Background Analysis of Issues Regarding Medication Administration Standards
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1. CMS' Conditions of Participation governing Respiratory Therapy Services at §482.57(b) and Medication Administration at §482.23(c)(1) require hospitals to have written policies for the administration of respiratory therapy services and the delivery of drugs and biologicals.

The Conditions of Participation for Respiratory Care Services require the hospital to meet the needs of patients in accordance with acceptable standards of practice. According to the CMS' Interpretative Guidelines, acceptable standards of practice include compliance with applicable standards that are set forth in Federal or State laws, regulations or guidelines, as well as standards and recommendations provided by nationally recognized professional organizations (e.g., American Medical Association, American Association for Respiratory Care, American Thoracic Association, etc.) The surveyors are required to determine that the type and amount of respiratory care provided meets the needs of the patient and is delivered in accordance with acceptable standards of practice.

In addition, the medication delivery standards require hospitals to administer all drugs and biologicals in accordance with the approved medical staff policies and procedures.

The AARC has a Uniform Reporting Manual that provides the time it takes to administer intermittent and continuous medication delivery. Times can average between 5 and 15 minutes. We do not, however, have specific written policies with respect to inhalation medication delivery timeframes before or after the scheduled delivery time. The generally accepted standard for the respiratory therapy profession as a whole for medication administration has always been 1 hour before or after the scheduled administration. To date, where hospitals have such policies, this practice is not considered "off schedule."

2. The Joint Commission (JAHCO) has established medication management policies that, among other things, state that medications are safely and accurately administered if they are consistent with the law and regulations or by hospital policy.

With respect to respiratory therapy medications, the AARC has developed a management guidance document titled "The Storage, Distribution, and Administration of Respiratory Medications (November 2004) intended to serve as a reference to assure that policies and procedures implemented are in compliance with The Joint Commission (JCAHO).

The JCAHO's Medication Standard MM 5.10 does not specify a specific time period for safe or accurate delivery of medications but leaves it up to the individual facility to establish.

3. The generally accepted standard for delivery of respiratory therapy medications of 1 hour before or after the scheduled administration time is evidenced by hospital policies established across the country.

The AARC conducted an informal survey of its management team to gather sample data on hospitals across the country having established separate respiratory therapy policies. Part of the survey data includes a group of for-profit hospitals primarily across the southern half of the United States from the west to the east. Of 34 hospitals in this group responding to the survey, 23 hospitals had established separate written policies for delivery of respiratory therapy medications that permitted on-time delivery 60 minutes before or after the scheduled. Only 11 reported using the 30-minute window.

Survey data collected by the AARC, in which hospitals have the 1-hour before and after policy, range from large teaching hospitals in urban areas with up to 800 beds to small 100-200 bed hospitals in rural areas. Separate from the response from the group hospital system noted above, we received replies from hospitals representing at least 17 states throughout the country. Overall, we know of at least 42 hospitals with the 1-hour delivery policy for respiratory therapy drugs.

A few examples of detailed policies where the administration times for inhalation drugs differ from the standard pharmacy schedule are provided in **Attachment 2**.

4. Medication errors threaten patient safety and are the cause of significant morbidity and mortality in hospitalized patients. In evaluating this problem, scientific evidence suggests that a medication error occurs if it is administered more than 60 minutes before or after the scheduled due time.

In 2002¹, a study was conducted of 36 hospitals and skilled nursing facilities that compared methods for detecting medication errors. The purpose of the study was to evaluate the validity and cost-effectiveness of three methods for detecting medication errors: incident report review, chart review, and direct observation. The study concluded that direct observation was the more accurate and efficient method. Medication error categories included unauthorized drug, extra dose, wrong dose, omission, wrong route, wrong form, wrong technique, and wrong time. As noted above, "wrong time" was defined as later than 1 hour before or after scheduled administration time. However, a 30-minute window was used for medications that were ordered before, with, or after a meal.

¹ Flynn, EA, Barker, KN, et. al. Comparison of methods for detecting medication errors in 36 hospitals and skilled nursing facilities. *Am J Health-Syst Pharm.* 2002;59:436-446.

The Veterans Administration is using Bar Code Medication Administration (BCMA) software to improve patient safety in its medical centers. According to an abstract published in the *Journal of Healthcare Information Management*², the system is designed to reduce medication administration errors by letting clinicians verify a patient's identity and validate medications against active orders. There are numerous management and accountability tools included in the BCMA data, which was collected in 2001. Among them is the "Medication Variance Log" which captures entries earlier or later than 60 minutes of the scheduled time. When the BCMA system is used, there was no report of medication errors.

Another study conducted in 2003³ looked at improving its medication errors in a 240-bed regional referral hospital and sharing best practices for implementing a patient safety initiative that targets point-of-care barcode technology (BPOC). By the end of 2001, the hospital had implemented the technology in all inpatient medical-surgical, telemetry, and intensive care units. From January 2002 through August 2002, they prevented more than 1,300 medication errors.

The first major finding with use of the bar-code technology was the number of doses nurses administered at least 60 minutes *after* the scheduled dose time. Although nurses administered medications as close to the scheduled time as possible, the staff learned that because the pharmacy uses standard medication administration times to avoid transcription and administration errors, nurses often were challenged to give all their patients several medications within the 60-minute dose due-time window. The authors noted that with pharmacy and therapeutics committee support, they increased the system alert "grace period" without any untoward effect on patient outcomes.

5. In establishing measurable elements for the timely delivery of medications, The Joint Commission's stresses that delays of more than 1 hour to administer certain drugs that require timing between doses, such as insulin, cardiac, hypertension, antibiotics, and others can be cause for concern.

In a 2006 book⁴ by JCAHO designed as a tool for international health care organizations to help improve their medication management processes and reduce medication errors, JACHO points out that "Medications are frequently given at scheduled times that are defined by policy with sometimes a 30 to 60 minute window." The discussion concludes that problems can occur when one nurse does all the administration for many patients and it takes more than 1 hour

² Johnson, CL, Carlson, RA, et. al. Using BCMA Software to Improve Patient Safety in Veterans Administration Medical Centers - Abstract. *Journal of Healthcare Information Management*. Vol. 16 No. 1.

³ Douglas, J, Larrabee, S. Patient Safety Series, Part 1 of 2 Implement Information Technology to Track and Reduce Medication Errors. *Nursing Management* 2003;34(5):36-40.

⁴ Understanding Medication Management in Your Health Care Organization. JCAHO. April 2006.

to complete the process. This can occur in large units where there is only one medication chart/trolley or one MAR book that is shared by multiple nurses. JACHO recommends that analysis and redesign of the process is essential to enable a safe and timely administration of medications.

6. The need to stagger administration schedules for respiratory therapists who may be responsible for patients across many care units or create different schedules for different units could reduce medication errors and is supported by a recent study.

Because respiratory therapy medications are delivered by the inhalation route, administration times can vary from five to fifteen minutes to deliver depending on the medication and delivery device. Delivery equipment and devices are unique (i.e., dry powder inhalers, metered dose inhalers, nebulizers) and require special skills of the respiratory therapist to administer, including patient assessment, that go beyond the time it takes to deliver a pill, an injection, or an IV.

While nurses generally deliver medications to the patients from one area or floor of the hospital, respiratory therapists only see patients having respiratory issues or are at high risk to develop respiratory issues. These patients are generally spread throughout the hospital on various floors. For example, a respiratory therapist may deliver medications to patients from several different areas of the hospital, several times each shift. The physician may also add a therapy to the patient's treatment regimen that is given together with the medication administration to enhance their collective effects. This combination would certainly not permit medication delivery to be accomplished 30 minutes before or after the scheduled due time.

A 2005 study⁵ evaluating the use of a bar-code point-of-care (BPOC) medication administration system supports the need for respiratory therapy schedules for medication delivery that differ from the standard pharmacy administration schedules.

The study looked at promising health care technologies that may help to reduce medication errors that occur. According to the authors, BPOC medication administration systems are designed to ensure that the right drug is being administered via the right route to the right patient in the right amount at the right time, e.g., the "five rights" of drug administration.

During the study, which examined data from six hospitals with fully implemented systems that are part of an integrated network of 27 not-for-profit community hospitals located in Northern California, errors were classified into seven types:

⁵ Sakowski J; Leonard T, et. al. Using a Bar-Coded Medication Administration System to Prevent Medication Errors. *Am J Health-Syst Pharm.* 2005;62(24):2619-2625

- Dose administered early or already given (give more than 1 hour early for scheduled orders or >10% early for as-needed orders.)
- No order
- Order discontinued or expired
- Wrong dose
- Wrong patient
- Wrong route
- Other (exceeding recommended dosage guidelines or unreadable bar code)

To optimize the system, audits included an assessment of the circumstances that led to each warning and were used to identify processes that could be improved to prevent future errors. The authors noted the following:

“In addition to order entry, alignment of BPOC with staffing constraints is needed to improve the medication administration process. For example, a disproportionate number of the early- and late-dose warnings involved respiratory therapy drugs. We found that many of these errors resulted from the incompatibility between programmed standard pharmacy administration schedules and respiratory therapist availability to meet the pharmacy schedule hospital-wide. If only one or two respiratory therapists are on duty to cover the entire hospital, it is impossible for them to deliver all of the scheduled treatments within the hospital network’s standard two-hour administration window, resulting in many early- or late-dose errors.

Staffing constraints must be considered when designing policies and procedures, especially those involving allied health care providers who may be responsible for patients across many care units. For example, implementing staggered administration schedules for respiratory therapy treatments or creating different schedules for different units may alleviate many unnecessary early- and late-dose errors.”

7. The Survey, Certification and Enforcement Branch of the Kansas City Regional Office interprets the Medication Administration policies in §482.23(c) to permit medications to be administered in accordance with accepted standards of practice, including the administration of drugs 60 minutes before and after the scheduled dose, if they are approved by the medical staff.

One of the Pharmacy Directors who responded to our survey noted that their hospital was in the process of revising its medication delivery policy. They wanted to make sure that “the medication would be considered on time if it were given 60 minutes prior to or 60 minutes after the scheduled dose” and that if such policy were followed, the hospital would be in compliance with the regulation. CMS staff confirmed that the interpretation was correct.

AARC was also told by one of our representatives in a 400-bed hospital in the western part of the country that they were surveyed in September last year and were not cited for this medication issue.

8. The State of North Carolina’s licensing requirements for hospitals requires respiratory therapy departments to develop written policies for medication administration.

There are several hospital licensing requirements regarding medication administration developed by the North Carolina Division of Health Services. The section dealing with respiratory therapy policies and procedures requires the facility to establish and maintain policies that include medication administration and safety. The pharmacy services and medication administration provisions also state “medications shall be scheduled and administered according to the established policies of the facility.” Therefore, we believe the regulations allow hospitals in the state of North Carolina to establish policies for the delivery of respiratory therapy medications that are based on generally accepted standards, including administration delivery times that can vary from the standard administration policy established by the medical staff.

Examples of Respiratory Therapy Policies Where Specific Treatment Schedules Have Been Established for Inhalation Medications

Example 1

Medications may be administered 1 hour before or after the scheduled time. The medication schedule may be modified for the following reasons:

- Patient preference, need, other scheduled interventions, or home therapy schedule
- Physician order for specific timed interventions
- Accommodation for new orders, stat, urgent or emergent situations

	Round 1	Round 2	Round 3	Round 4	Round 5	Round 6
	0700-1100	1100-1500	1500-1900	1900-2300	2300-0300	0300-0700
Q12H	X			X		
BID	X			X		
Q8H	X		X		X	
TID	X	X or	X	X		
Q6H	X	X or	X	X or	X	X
QID	X	X	X	X		
Q4H	X	X	X	X	X	X

Example 2

Inhalation Medication Schedule (RCPs/Cardiopulmonary):

QID: 0700, 1100, 1500, 1900

TID: 0800, 1400, 2000

BID: 0900, 2100

Q (hourly) i.e. Q2, Q4, etc: given based on last dose administration time, adhering to frequency ordered by physician.

NOTE: Inhalation medications can be administered up to one hour before, and/or one hour after the times noted above, to ensure proper scheduling of all therapy for all patients.

Example 3

Medications given later than 1 hour after defined Respiratory medication frequencies (as stated below) are considered late/missed therapy and must be documented in the missed therapy log book located in the department. The reason for the missed therapy must be noted and periodic review of missed therapy is done as part of the department PI program so as to examine process improvement if possible.

1. Q4hr is given: 7a-11a-3p-7p-11p-3a
2. Q4hr w/a: 7a-11a-3p-7p-11p
3. QID: 8a-12p-4p-8p
4. Q6hr: 8a-2p-8p-2a
5. TID: 8a-4p-8p
6. BID: 9a-9p

Example 4

The following are standard times for administration of treatments by ordered frequency. The times may vary one hour before or after the standard time.

- Q2: 8 - 10 - 12 - 2 - 4 - 6 - 8 - etc.
 Q3: 7 - 10 - 1 - 4 - 7 - 10 - 1 - 4
 Q4: 8 - 12 - 4 - 8 - 12 - 4
 Q6: 8 - 2 - 8 - 2
 QID (Q4 w/a): 8a - 12 - 4 - 8p
 TID (Q6 w/a): 8a - 2 - 8p
 BID : 8a - 8p

Example 5

The department policy id “on time” is as per the chart below:

TREATMENT FREQUENCY	Treatment Period A 6:30-10:30	Treatment Period B 10:31 – 14:30	Treatment Period C 14:31 – 18:00	Treatment Period D 18:01 – 22:00	Treatment Period E 22:01 – 2:30	Treatment Period F 2:30 – 6:30
QID	1	1	1	1		
TID	1		1	1		
BID		1			1	
Q2 HR	2	2	2	2	2	2
Q3 HR	Every three (3) hours after initial treatment ± ½ hour					
Q4 HR	Every four (4) hours after initial treatment ± ½ hour					
Q6 HR	Every six hours after initial treatment ± 1 hour					
Q8 HR	Every eight (8) hours after initial treatment ±1 hour					
Q12 HR	Every twelve (12) hours after initial treatment ± 1 hour					
DAILY	One (1) time on Period A or B					

American Association for Respiratory Care

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Position Statement

Inhaled Medication Administration Schedules

Inhaled medication administration incorporates a unique methodology and has a recognized time standard between nine and twenty minutes depending on the delivery device used for administration. It is the position of the AARC that medical facilities need to establish written policies and procedures for the safe and timely administration of inhaled medications that are appropriate for the facility and approved by the medical staff. These policies may differ from standard medication administration schedules and time frames, but must be implemented so that medications are administered as prescribed – i.e. Q 1 hour, QID, BID, etc. If a facility establishes an alternative schedule for the safe and effective delivery of inhaled medications, the AARC recommends that the inhaled medication delivery schedule window not exceed 60 minutes before or after the scheduled medication delivery due time for medications prescribed at an interval greater than or equal to four hours.

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BOARD OF MEDICAL ADVISORS

The Board of Medical Advisors of the American Association for Respiratory Care includes representatives who are appointed by their respective organizations to sit on the Board. Their input is based on individual medical expertise and should not be construed to be representative of their organizations as a whole.

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American Society of Anesthesiologists

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American Thoracic Society

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