Laboratory Test Requirements Outdated

Statutory Language: Social Security Act 1861(aa)(2)(G) directly provides routine diagnostic services, including clinical laboratory services, as prescribed in regulations by the Secretary, and has prompt access to additional diagnostic services from facilities meeting requirements under this title

Regulatory Language: 42 CFR 391.9(c)(2) These requirements apply to RHCs but not to FQHCs. The RHC provides laboratory services in accordance with part 493 of this chapter, which implements the provisions of section 353 of the Public Health Services Act. The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient including:

(i) Chemical examinations of urine by stick or tablet method or both (including urine ketones);
(ii) Hemoglobin or hematocrit;
(iii) Blood glucose;
(iv) Examination of stool specimens for occult blood;
(v) Pregnancy tests; and
(vi) Primary culturing for transmittal to a certified laboratory.

Proposed Language: Remove ~~**(ii)** Hemoglobin or hematocrit~~ and
Insert: The RHC is able to provide basic laboratory services essential to the immediate diagnosis and treatment of the patient including:

Discussion: The current regulatory language is outdated. Hemoglobin or hematocrit lab tests are rarely ordered on their own. Instead, they are ordered as part of a comprehensive blood test. Most RHCs are not equipped to provide full comprehensive blood tests and thus the hemoglobin and hematocrit equipment is wasted and thrown away.

The statutory language is clear that the Secretary has the authority to determine what would be considered a "routine diagnostic service." As such, we ask the Secretary to consider updating the laboratory services are required to be able to provide on-site.

It is also sometimes more cost-effective for an RHC to send out certain lab tests for performance by an outside lab. The inserted language retains the requirement that the RHC make the listed lab services available on-site but allows the RHC the flexibility to send the lab test to an outside lab should this be deemed more appropriate or cost-effective in a particular situation.

1009 Duke Street
Alexandria VA 22314
202-543-0248
bf@narhc.org

Emergency Services Requirement Burdensome and Rigid

Statutory Language: Social Security Act 1861(aa)(2)(H) in compliance with State and Federal law, has available for administering to patients of the clinic at least such drugs and biologicals as are determined by the Secretary to be necessary for the treatment of emergency cases (as defined in regulations) and has appropriate procedures or arrangements for storing, administering, and dispensing any drugs and biologicals;

Regulatory Language: 42 CFR 491.9(c)(3) The clinic or center provides medical emergency procedures as a first response to common life-threatening injuries and acute illness and has available the drugs and biologicals commonly used in life saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.

Proposed Language: The clinic or center provides medical emergency procedures as a first response to common life-threatening injuries and acute illness and has available the drugs and biologicals commonly used in life saving procedures, as determined by the group of professional personnel responsible for providing advice on patient care policies as defined in 491.9(b)(2). ~~such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.~~

Discussion: Recent guidance has interpreted the words "such as" to mean that each of the items listed is a required category of drugs and biologicals. The guidance specifically mentions that a RHC must have snake antidote, which is a very costly antidote that will not be used in the vast majority of cases. This will cost tens of thousands of dollars per RHC. Attached is a survey where we asked RHCs to identify the frequency with which they have had patients with snake bites present themselves. As you can see 97% of respondents indicated that they had not seen a snake bite in the last year. CroFab, the antidote used for snake bites, can cost upwards of $4,000 per vial, and a shelf life of 24 - 30 months.

Furthermore, the current regulation requires RHCs to have emetics on hand. Emetics are no longer standard of care for the treatment for patients that digest toxic or poisonous substances. Updating the regulations in a sustainable way, that allows RHCs to maintain standard of care not just today but decades from now should be considered.

RHCs adjacent to a hospital emergency room would be required to stock these drugs and biologicals. This would also apply in states that do not even have poisonous snakes (Hawaii).

We believe that the best way for the Secretary to determine the drugs and biologicals necessary is to give that responsibility to the personnel responsible for providing advice on patient care policies at the RHC. These individuals should have the discretion to determine the drugs and biologicals that are necessary based on the community need and circumstances.

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RHCs Must Issue W-2s to PAs and NPs

Statutory Language: Social Security Act 1861(aa)(2) For the purposes of this title, such term includes only a facility which…(iii) employs a physician assistant or nurse practitioner.

Regulatory Language: 42 CFR 491.8(a)(3) The physician assistant, nurse practitioner, nurse-midwife, clinical social worker or clinical psychologist member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the clinic or center. In the case of a clinic, at least one physician assistant or nurse practitioner must be an employee of the clinic.

Proposed Language: Strike the last sentence of 491.8(a)(3): ~~In the case of a clinic, at least one physician assistant or nurse practitioner must be an employee of the clinic.~~

Discussion: We believe that Congress by using the term "employ" meant that the RHC "utilize" or "use" PAs or NPs. CMS has taken the position that a PA or NP must be "employed" as evidenced by the issuance of a W-2. This prevents PAs or NPs from being independent contractors.

At one time, CMS required all PAs or NPs to be employed by the RHC but as part of an earlier regulatory relief initiative, relaxed the policy so that only one PA or NP is required to be employed. We do not believe this went far enough.

This requirement has been particularly problematic when a physician owned RHC is sold to a hospital and then the hospital seeks to retain the physician and his/her NP or PA as contracted providers to the RHC. The Physician can be contracted but the PA or NP must convert to being a hospital employee. This forces the PA or NP into an employer/employee relationship with the hospital when the PA or NP would rather be an independent contractor or an employee or partner in a separate corporation that contracts back to the hospital-based RHC.

42 CFR 491.8(a)(6) requires that RHCs have "a nurse practitioner, physician assistant, or certified nurse-midwife available to furnish patient care services at least 50 percent of the time the RHC operates." We believe that this regulation satisfies the intent of Congress which was to ensure that RHCs make better use of NPs, PAs, and CNMs. We do not believe Congress intended to dictate employment arrangements, rather, that Congress wanted RHCs to utilize PAs, NPs or CNMs.

1009 Duke Street
Alexandria VA 22314
202-543-0248
bf@narhc.org

De Facto Physician Onsite Requirement

Statutory Language: Social Security Act 1861(aa)(2) The term "rural health clinic" means a facility which-**(B)** in the case of a facility which is not a physician-directed clinic, has an arrangement (consistent with the provisions of State and local law relative to the practice, performance, and delivery of health services) with one or more physicians (as defined in subsection (r)(1)) under which provision is made for the periodic review by such physicians of covered services furnished by physician assistants and nurse practitioners, the supervision and guidance by such physicians of physician assistants and nurse practitioners, the preparation by such physicians of such medical orders for care and treatment of clinic patients as may be necessary, and the availability of such physicians for such referral of and consultation for patients as is necessary and for advice and assistance in the management of medical emergencies; and, in the case of a physician-directed clinic, has one or more of its staff physicians perform the activities accomplished through such an arrangement;

Regulatory Language: 42 CFR 491.8(b)(3) Periodically reviews the clinic's or center's patient records, provides medical orders, and provides medical care services to the patients of the clinic or center.

Proposed Language: Periodically reviews the clinic's or center's patient records, and provides medical orders~~, and provides medical care services to the patients of the clinic or center~~.

Discussion: The statutory language makes it clear that clinics not directed by a physician must have an arrangement with one or more physicians "consistent with the provisions of State and local law relative to the practice, performance, and delivery of health services."

State laws governing PA and NP scope of practice and physician supervision/collaboration have evolved dramatically over the past 40 years. The RHC regulations affecting the physician, PA/NP relationship have been largely unchanged since they were originally adopted nearly 40 years ago.

CMS' recent interpretation of this section establishes a de facto physician on-site requirement by mandating that the physician "provide medical care services to the patients of the clinic or center."

This regulatory language was developed and finalized at a time when most states did not have any statutory or regulatory structure governing PA or NP practice. As a result, the federal regulations were written in a very prescriptive manner. This is no longer necessary because we have since developed robust state laws and regulations governing nurse practitioner and physician assistant practices. These antiquated federal requirements conflict with the more mature state rules that govern PA and NP practices today.

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202-543-0248
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Emergency Preparedness Requirement Excessively Burdensome

Statutory Language: **Social Security Act 1861(aa)(2)(K)** meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are furnished services by the clinic.

Regulatory Language: 42 CFR 491.12(d)(2) The RHC/FQHC must conduct exercises to test the emergency plan at least annually. The RHC/FQHC must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the RHC/FQHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the RHC/FQHC is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the RHC/FQHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the RHC/FQHC's emergency plan, as needed.

Proposed Language:

(i) Participate in one exercise that may include, but is not limited to following:

(A) A full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(ii) Analyze the RHC/FQHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the RHC/FQHC's emergency plan, as needed.

Discussion: The OMB estimated that participation the new emergency preparedness rules would cost over $4,000 per RHC per year. We have found that clinics are struggling most with the requirement to perform emergency exercises. Reducing the exercise requirements to one per year will provide much needed regulatory relief to RHCs without compromising emergency preparedness.

Emergency preparedness rules were greatly expanded in 2016 and went into effect in 2017. It has been difficult for RHCs to meet all the new requirements, and we have heard that organizing meaningful emergency drills or exercises is one of the most time consuming parts. Lowering the number of drills/exercises to one per year would help RHCs struggling to find the time and bandwidth to maintain compliance.

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