National Organization of
State Offices of Rural Health

August 15, 2016

Centers for Medicare & Medicaid Services,

SUBJECT: Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care CMS-3295-P

To Whom it May Concern:

The National Organization of State Offices of Rural Health (NOSORH) is the membership association of the fifty State Offices of Rural Health. Our mission is to work with the fifty State Offices of Rural Health to improve health in rural America. State Offices of Rural Health are anchors of information and neutral observers and conveners for rural health. They support collaboration, information dissemination and technical assistance to rural communities and health care providers across the nation including critical access hospitals, certified rural health clinics, oral health and other providers. More importantly their technical assistance efforts have been key to engaging critical access hospitals and other rural providers in voluntary quality reporting.

NOSORH submits these comments to ensure the unique needs of these rural providers and their important role in improving care for millions of rural Americans is understood.

Thank you for the opportunity to comment. If we can provide additional information on the impact of proposed regulations for rural and underserved communities please feel free to email teryle@nosorh.org or call for assistance.

Sincerely,

Teryl E. Eisinger, MA
Executive Director
National Organization of State Offices of Rural Health

Draft NOSORH Comments on Proposed Changes to Hospital and Critical Access Hospital Conditions of Participation

Introduction

The Notice of Proposed Rulemaking (NPRM) published by the Centers for Medicare and Medicaid Services (CMS) on June 16, 2016 sets out new and revised Medicare and Medicaid Conditions of Participation (CoPs) for hospitals and Critical Access Hospitals (CAHs). Several of these requirements have operational implications for rural hospitals and rural CAHs. In this communication the National Organization of State Offices of Rural Health (NOSORH) makes specific comment on how the proposals in the NPRM would affect these rural facilities and submits recommendations on how the requirements can be implemented in a way which does not create excessive burden.

Proposed Quality Assessment and Performance Improvement (QAPI) Program CoPs for CAHs(§ 485.641) and Hospitals (§ 482.21)

General Comments: NOSORH strongly supports the development of appropriate quality assessment and performance improvement in rural hospitals and CAHs. The proposed requirements in these sections set a reasonable framework for implementing QAPI in rural facilities. The success of the framework in rural hospitals and CAHs will depend upon how that framework is implemented. In particular, it will depend upon how CMS interprets the requirements. In several places the proposed language speaks to the establishment of procedures which reflect the scope and complexity of a hospital or CAHs operations. In addition, the language requires that adequate resources be allocated to QAPI activities. The interpretation of these ideas will be of great importance to rural hospitals and CAHs.
Recommendations: To assure that the proposed QAPI CoPs for rural hospitals and CAHs are appropriate and feasible, NOSORH makes the following recommendations:

- **Appropriateness of Data Collection and Analysis Requirements**: Required reporting, monitoring and assessment efforts should be appropriate for the complexity and scope of smaller, low-volume hospital and CAH operations. These efforts should be of a magnitude that is feasible within the more limited resources of these facilities. This may mean that a separate data collection and reporting scheme may need to be established for smaller facilities, limited to the measures relevant to these facilities.

  NOSORH was pleased to see that CMS acknowledges in § 485.641 the Medicare Beneficiary Quality Improvement Project (MBQIP) reporting system used by many CAHs. NOSORH is encouraged that CMS recognizes it as appropriate system for CAHs. MBQIP is a reduced set of CAH-relevant measures which can be managed within the resources of a smaller facility. This includes both the limited personnel and financial resources of smaller operations.
  NOSORH recommends that a similar approach be taken in the interpretation of what reporting requirements are appropriate for smaller rural hospitals. Smaller rural hospitals have limits that are not very different from those of CAHs. While these hospitals have been meeting QAPI requirements since 2003, the

44648 Mound Road, #114 | Sterling Heights, MI 48314-1322 | TEL 586-336-4627 | FAX 586-336-4629

implementation additional requirements proposed in § 482.21 should be considered in light of the operational complexity and resource availability of these facilities.

- **Appropriate Scope of Performance Improvement Projects**: Performance improvement projects in CAHs and small rural hospitals should be appropriate for the operational complexity and scope of CAHs and smaller rural hospitals. These projects should be of a scope that is achievable within the more limited resources of these facilities. NOSORH notes the language for CAHs in§ 485.641(e) which recognizes that these projects should be proportional to the scope and complexity of a CAHs services and operations. This is a positive approach in the guidance which NOSORH recommends be extended to smaller rural hospitals. The adequacy of available resources, including both personnel and financial, should also be a consideration.

Proposed Infection Prevention and Control CoPs for CAHs (§ 485.640 (a) (1)) and Hospitals (§ 482.42(a))

General Comments: NOSORH and its member State Offices of Rural Health work with rural hospitals and CAHs on quality improvement issues, including infection prevention and control. The proposed requirements in this section set a reasonable framework for prevention control and improvement in these rural facilities. As with QAPI, the usefulness of the framework will depend upon its interpretation in smaller facilities with a narrow range of services and limited resources.

Recommendations: To assure that the proposed infection prevention and control CoPs for rural hospitals and CAHs are appropriate and feasible, NOSORH makes the following recommendations:

- **Appropriateness of Leadership, Staffing and Program Requirements**: Staffing and leadership of a facility's infection prevention and control efforts should be appropriate for the complexity and scope of smaller, low-volume operations. These efforts should be of a magnitude that is feasible within the more limited resources of these facilities.

  The proposed requirements for CAHs call for appointment of an individual to lead the efforts who is qualified through education, training, experience, or certified in infection, prevention and control. In rural communities, finding someone to meet specific educational or certification requirements can be challenging. The language of the requirements is general, and can be interpreted to permit leadership of the effort by individuals who are part-time or contracted. It can also be interpreted to permit leadership by individuals, trained in other disciplines, who receive supplemental training in infection prevention and control. These different approaches should be permitted in CAHs.

  The proposed CAH requirements in this area reference CDC guidance for appropriate prevention and control efforts. The CDC guidance is scalable, and should be feasible for most CAHs. NOSORH appreciates the choice of this framework for CAHs.

44648 Mound Road, #114 | Sterling Heights, MI 48314-1322 | TEL 586-336-4627 | FAX 586-336-4629

NOSORH recommends that the same flexibility be extended to smaller rural hospitals. The infection prevention and control requirements for hospitals are more stringent than are those for CAHs, requiring adherence to more complex controls. This could create problems for smaller rural hospitals. NOSORH is pleased to see language in the requirements which permit an infection prevention and control program which "reflects the scope and complexity of the hospital services provided." This should provide the flexibility needed to adapt the requirements to smaller facilities.

Proposed Antibiotic Stewardship Program CoPs for CAHs (§ 485.640 (a) (1)) and Hospitals (§ 482.42(b))

General Comments: The proposed CoP changes for CAHs and rural hospitals set additional responsibilities for the establishment of an antibiotic stewardship program to improve hospital antibiotic-prescribing practices and curb patient risk for potentially life-threatening, antibiotic-resistant infections. This program is to be linked and coordinated with infection prevention and control efforts. It is to be conducted according to nationally recognized guidelines for appropriate antibiotic use. The proposal requires leadership of the program by an individual who is appropriately trained and skilled. The proposed CoP changes include these requirements together with the infection prevention control requirements, but NOSORH sees them as significant enough by themselves to warrant separate comment.

Recommendations: NOSORH recognizes the importance of antibiotic stewardship in CAHs and rural hospitals. NOSORH supports the establishment of requirements that are appropriate for smaller facilities with a narrow range of services and limited resources. To assure that the proposed antibiotic stewardship program CoPs for rural hospitals and CAHs are appropriate and feasible, NOSORH makes the following recommendations:

- **Appropriateness of Leadership and Program Requirements**: NOSORH recommends that leadership and program requirements for a facility's antibiotic stewardship effort be appropriate for the complexity and scope of smaller, low-volume operations. These efforts should be of a magnitude that is feasible within the more limited resources of these facilities. Requirements should permit the appointment of program leadership of individuals who are part-time or contracted. They should also permit leadership by individuals, trained in other disciplines, who receive supplemental training in antibiotic stewardship.

  The language of the proposed changes suggests that the leadership of the antibiotic stewardship program should be the same as the leadership of the infection prevention and control efforts. This may not always be feasible in a CAH or small rural hospital. NOSORH recommends that the requirements permit different individuals to lead the two efforts, as long as the efforts are well coordinated and integrated into QAPI under the oversight of the appropriate governing body.

The proposed guidance understands that "the CAH's stewardship program would have to reflect the scope and complexity of services offered." This is very positive, as it assures that the program effort and the standards used reflect the scale of CAH operation. NOSORH recommends that the same flexibility be extended to the requirements for small rural hospitals.