NOSORH

National Organization of
State Offices of Rural Health

August 24, 2018

TO: Centers for Medicare & Medicaid Services

FROM: Teryl Eisinger, Executive Director

Subject: Centers for Medicare and Medicaid Services (CMS) Request for Information (RFI), Stark CMS–1720–NC

The National Organization of State Offices of Rural Health (NOSORH) is the membership association of the fifty State Offices of Rural Health (SORH). 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. SORH are dedicated to addressing the issues that impact the recruitment and retention of rural physicians and primary care providers and ensuring the vitality of the hospitals and clinics they serve. SORH 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.

NOSORH submits these comments are to ensure issues that the unique issues which impact rural communities throughout rural America are 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 and the providers who serve them please feel free to email teryle@nosorh.org or call for assistance.

Sincerely,

Teryl Eisinger

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

www.nosorh.org

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

NOSORH Comments on CMS Request for Information Regarding the Physician Self-Referral Law

Overview

On June 25, 2018 the Centers for Medicare and Medicaid Services (CMS) issued a Request for Information (RFI), CMS–1720–NC, seeking input on how the Physician Self-Referral Law, also known as the Stark Law, could be modified to reduce unnecessary regulatory impact and burden. The RFI solicits input with particular comments related to how the burdens under Stark may be creating barriers to value-based alternative payment methodologies (APMs). CMS has created multiple opportunities for Medicare and Medicaid APMs including Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program (MSSP) and Bundled Care demonstrations. The RFI solicits specific comments relevant to how Stark Law requirements might create unnecessary barriers to value-based payment systems.

In this communication the National Organization of State Offices of Rural Health (NOSORH) makes specific comment and recommendation related to this RFI.

NOSORH believes that the Stark Law creates some unique challenges for the participation of rural health providers/facilities in value-based alternative payment methodologies. In addition, NOSORH believes that related Federal fraud, abuse and antitrust requirements create additional unnecessary barriers to participation. The aim of any rule/statutory changes should be to permit all rural health service providers/facilities to participate in alternative payment mechanisms – particularly value-based payment arrangements. Participation should be permitted in all Medicare, Medicaid and private commercial APMs. Participation should be permitted in both risk-assuming and upside-only shared savings arrangements.

Value-based APMs provide improved care for patients in a cost-effective manner, all within the goals of the Patient Protection and Affordable Care Act. Regulatory and statutory barriers to participation should be eliminated to assure that rural residents have equal access to these arrangements. Changes in statute, rule and policy should be considered that will permit rural health service providers/facilities to participate in:

- *Horizontal* APM arrangements ***within*** rural service areas.
- *Vertical* APM arrangements ***between*** rural areas and other regional providers and facilities. Under these arrangements referrals can be made upstream to non-rural services with coordinated return referrals back to rural areas.

In the comments presented below NOSORH highlights key factors which should be considered and suggests specific approaches for assuring that changes in Stark and related requirements will be successful in rural/frontier communities.

Key Considerations and Recommendations

Expansion of Rural Safe Harbors and Exceptions: NOSORH believes that there is a need to develop standardized safe harbors/exceptions for rural areas under all relevant fraud, abuse and antitrust requirements, including the Stark Law.

- **Discussion:** Stark Law provisions currently provide a partial rural exception. Stark exempts physician referrals horizontally within a defined rural area. While these Stark exemptions are useful, they do not adequately provide a safe harbor for other APM arrangements, including vertical regional arrangements. This can create barriers to value-based payment arrangements which would otherwise provide a pro-competitive integrated method to raise quality and lower costs.

In addition, although a given arrangement might meet Stark rural exception requirements, it might run into problems with other Federal fraud, abuse and antitrust requirements, including those established under the Anti-Kickback Law (AKL), Civil Monetary Penalties Law (CMP), and antitrust laws. This complex of fraud, abuse and antitrust requirements makes it difficult for rural health service providers/facilities to participate effectively in value-based performance payment arrangements. The cost of establishing conforming alternative payment arrangements can be significant and may form a barrier for rural provider/facility participation in these arrangements.

- **Recommendation:** Rural areas should have exceptions which permit both vertical and horizontal collaborations for purposes of value or performance-based compensation arrangements. **NOSORH recommends the creation of a unified set of rural safe harbors and exceptions for the full range of Federal health service fraud, abuse and antitrust requirements.**

Establish Consistent Rural Definitions for Safe Harbors/Exceptions: NOSORH believes that there is a need to develop a consistent definition of rural to be used in the expanded set of rural safe harbors/expansions.

- **Discussion**: There are currently two Federal fraud, abuse and antitrust requirements which make provision for rural exceptions – the Stark Law and Federal antitrust laws. Unfortunately, the definition of rural for these exceptions is vastly different.

  Under the Stark Law a rural exception is established for non-urban areas, i.e. areas that are not part of a Metropolitan Statistical Area. In contrast, for antitrust purposes, "rural area" means any county containing at least one zip code that has been classified as "isolated rural," or "other small rural," according to the WWAMI Rural Health Research Center of the University of Washington's seven category classification. These are zip codes that have a Rural Urban Commuting Area ("RUCA") code of 10.0, 10.2–10.6, 8.0, 8.2–8.4, or 9.0–9.2. This is a much more restrictive definition of rural, excluding many areas which would meet the Stark Law criterion.

  As an example, Santa Rosa, New Mexico is a town of 2,848 people in a designated frontier area. It is 137 miles from Albuquerque and the nearest MSA. As such it meets the criterion for the rural exception under Stark. Santa Rosa has a small county hospital, which is the only inpatient facility for many miles. There is a single physician in private practice in town. Most specialty care and surgical services are provided through referrals out of the area. The Santa Rosa service area would be an excellent candidate for participation in a regional alternative payment arrangement.

  Unfortunately, the Santa Rosa area has a RUCA designation of 7, and is not eligible as a safety zone for antitrust enforcement. This example highlights the importance of having standard, inclusive rural definitions. It is not enough to expand rural safe harbors/exceptions for Federal fraud, abuse and antitrust requirements - the definitions of rural for the different requirements need to be consistent.

- **Recommendation**: **NOSORH recommends that uniform definition of eligible rural area be used as the basis for the expanded set of rural safe harbor/exceptions. The Stark Law definition of rural should be used for this is standard definition.**

Develop New Exceptions/Safe Harbors for Value-Based Payments: NOSORH believes that it is not enough to establish exceptions for rural providers/facilities. There needs to be adequate flexibility for regional arrangements to be established between rural and urban areas.

- **Discussion**: There are Stark Law exceptions possible for some APM arrangements, including some Federally participating Accountable Care Organizations under the Medicare Shared Savings Program (MSSP). In addition, there have been multiple Department of Health and Human Services / Office of the Inspector General Bulletin and opinion issuances providing exceptions from a broader set of fraud and abuse requirements. These exceptions are based on specific contractual, structural and methodological arrangements for value-based Medicare and Medicaid gainsharing. Under this piecemeal guidance, applicants seeking the broadest range of waiver may be required to submit multiple applications to multiple Federal agencies.

  The exceptions provided under this patchwork guidance are not comprehensive – they do not provide relief for the full range of different value-based payment arrangements currently being developed for Medicare, Medicaid and commercial payments. There is a need to establish a consistent, comprehensive set of exceptions for all Federal fraud, abuse and antitrust requirements covering all value-based payment arrangements. These exceptions must be established for the Stark Law as well as for the Anti-Kickback Law (AKL), Civil Monetary Penalties Law (CMP), and antitrust laws.

- **Recommendation**: **NOSORH recommends that a consistent, comprehensive, set of safe harbors/exceptions be established for all value-based payment arrangements. These safe harbors/exceptions should be for the full set of Federal health service fraud, abuse and antitrust requirements, and should be applicable to value-based alternative payment arrangements for Medicare, Medicaid and commercial payments.**

Establish Non-Gainsharing Safe Harbors/Exceptions: NOSORH believes that safe harbors/exceptions should be extended to APM support other than payment arrangements.

- **Discussion:** NOSORH recognizes that safe harbors/exceptions should not be limited to provider payments. As part of APMs, providers/facilities may receive additional, non-payment support, including health information technology. APM networks often provide this type of support to rural providers/facilities/agencies as an essential component of care improvement and efficiency. This type of support is necessary for effective participation in coordinated care arrangements. NOSORH believes that these care coordination supports must be explicitly recognized in safe harbors/exceptions for Federal fraud, abuse and antitrust requirements.

- **Recommendation: NOSORH recommends that safe harbors/exceptions should be established for APM participation support other than gainsharing. This could include APM network support for HIT and electronic health records.**