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Valuation of Rural Health Clinics: Regulatory

As discussed in the first installment of this five-part series, *rural health clinics* (RHCs) are statutorily-created entities, established via the *Rural Health Clinic Service Act of 1977*.[1] These providers face a range of federal and state legal and regulatory constraints, which affect their formation, operation, and transactions. This *Health Capital Topics* article will discuss two important regulatory issues affecting RHCs – licensure requirements and fraud and abuse law compliance.

Licensing of RHCs

There are a number of requirements that RHCs must meet in order to become licensed and maintain Medicare certification. First, the RHC must be located in a rural, underserved area (as defined by the *U.S. Census Bureau* and the *Health Resources and Services Administration*).[2] Additionally, the clinic must utilize *non-physician providers* (NPPs) in rendering patient services, including nurse practitioners (NP), physician assistants (PA), and certified nurse midwives (CNM) – in fact, the RHC is required to be staffed with these NPPs a majority of the time.[3] As regards the services to be offered, RHCs must provide outpatient primary care services, as well as basic laboratory and diagnostic services such as:

(1) Chemical examination of urine by stick or tablet method or both;

(2) Hemoglobin or hematocrit;

(3) Blood sugar;

(4) Examination of stool specimens for occult blood;

(5) Pregnancy tests; and,

(6) Primary culturing for transmittal to a certified laboratory.[4]

The advantage to licensing an RHC is that the clinic may then receive (enhanced) Medicare and Medicaid reimbursement, as discussed in the May 2019 issue of *Health Capital Topics*.[5]

Fraud and Abuse Laws

Fraud and abuse laws, specifically those related to the federal *Anti-Kickback Statute* (AKS) and physician self-referral laws (the "*Stark Law*"), may have the greatest impact on the operations of healthcare organizations. The AKS and Stark Law are generally concerned with the same issue – the financial motivation behind patient referrals. However, while the AKS is broadly applied to payments between providers or suppliers in the healthcare industry and relates to any item or service that may be paid for under any federal healthcare program, the Stark Law specifically addresses the referrals from physicians to entities with which the physician has a financial relationship for the provision of defined services that are paid for by the Medicare program.[6] Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.[7]

The AKS makes it a felony for any person to "*knowingly and willfully*" solicit or receive, or to offer or pay, any "*remuneration*," directly or indirectly, in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program.[8] Violations of the AKS are punishable by up to five years in prison, criminal fines up to $25,000, or both.[9] Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[10] In response to these concerns, Congress created a number of statutory exceptions and delegated authority to the HHS to protect certain business arrangements by means of promulgating several *safe harbors*.[11] These *safe harbors* set out regulatory criteria that, if met, shield an arrangement from regulatory liability, and are meant to protect transactional arrangements unlikely to result in fraud or abuse.[12]

Two AKS *safe harbors* that are specifically applicable to RHCs include the *practitioner recruitment safe harbor* and the *joint venture safe harbor*. The *practitioner recruitment safe harbor* protects recruitment payments to physicians to convince them to locate to a *health professional shortage area* (HPSA).[13] Additionally, the *joint venture safe harbor* allows for investments in joint ventures that are located in medically underserved areas (provided they meet several requirements). In effect, this safe harbor allows RHCs to attract and obtain needed capital (often from local physicians).[14]

The Stark Law prohibits physicians from referring Medicare patients to entities with which the physicians or their family members have a financial relationship for the provision of *designated health services* (DHS).[15]

The Stark Law contains a large number of *exceptions*, which describe ownership interests, compensation arrangements, and forms of remuneration to which the Stark Law does not apply.[16] Similar to the AKS *safe harbors*, without these *exceptions*, the Stark Law may prohibit legitimate business arrangements. However,

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unlike the AKS safe harbors, an arrangement must fully fall within one of the *exceptions* in order to be shielded from enforcement of the Stark Law.[17]

Two Stark Law exceptions that are of particular importance to RHCs include the "*assistance to compensate a nonphysician practitioner [NPP]*" *exception* and the *Rural Provider exception*. The 2016 *Medicare Physician Fee Schedule* (MPFS) final rule added the NPP exception, which permits "*remuneration provided by a hospital...or RHC to a physician to assist the physician with compensating an NPP to provide primary care services or mental health care services to patients of the physician's practice*."[18] This exception arises out of the need to increase access to primary care services, a central goal of the ACA, in light of projections of a shortage of primary care physicians.[19] Additionally, the *Rural Provider exception* concerns referrals by physicians with an ownership/investment interest in an enterprise, for DHS "*...furnished in a rural area... if...substantially all of the [DHS] furnished by the entity are furnished to individuals residing in such a rural area…*"[20]

CONCLUSION

Despite the stance of the current presidential administration toward de-regulating healthcare,[21] the regulatory scrutiny of healthcare entities (especially with regard to fraud and abuse violations) has generally increased in recent years. Therefore, under current regulation, the severe penalties that may be levied against healthcare providers, including RHCs, under these various federal and state fraud and abuse laws are still a risk factor for RHCs, as well as for potential investors in such entities.

1 "Rural Health Clinics (RHCs)" Rural Health Information Hub, https://www.ruralhealthinfo.org/topics/rural-health-clinics (Accessed 3/19/19).
2 *Ibid*; "Rural Health Clinic" MLN Fact Sheet, ICN 006398, January 2018, available at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/RuralHlthClinfctsht.pdf (Accessed 12/14/18), p. 2.
3 Rural Health Information Hub, (Accessed 12/14/18).
4 Rural Health Information Hub, (Accessed 12/14/18); MLN Fact Sheet, January 2018, p. 2-3.
5 "Valuation of Rural Health Clinics: Reimbursement" Health Capital Topics, Vol. 12, Issue 5, https://www.healthcapital.com/hcc/newsletter/05_19/HTML/CLINIC/convert_hc_topics_rhc_reimbursement_5.23.19.php (Accessed 6/18/19).
6 "Fundamentals of the Stark Law and Anti-Kickback Statute" By Asha B. Scielzo, American Health Lawyers Association, Fundamentals of Health Law: Washington, DC, November 2014, https://www.healthlawyers.org/Events/Programs/Materials/Documents/FHL14/scielzo_slides.pdf (Accessed 12/9/15), p. 4-6, 17, 19, 42.
7 *Ibid*, p. 42.
8 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(1) (2013).
9 *Ibid.*
10 "Re: OIG Advisory Opinion No. 15-10" By Gregory E. Demske, Chief counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, http://oig.hhs.gov/fraud/docs/advisoryopinions/15/AdvOpn15-10.pdf (Accessed 12/9/15), p. 5.
11 *Ibid.*
12 "Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule" Federal Register, Vol. 64, No. 223 (November 19, 1999), p. 63518, 63520. Note that, failure to meet all of the requirements of a safe harbor does not necessarily render an arrangement illegal.
13 "Exceptions" 42 CFR § 1001.952(e)(2)(iii).
14 "Federal Anti-Kickback Law and Regulatory Safe Harbors" Office of Inspector General, Office of Public Affairs, Fact Sheet, November 1999, https://oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm (Accessed 6/18/19).
15 If a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral "CRS Report for Congress: Medicare: Physician Self-Referral ("Stark I and II")" By Jennifer O'Sullivan, Congressional Research Service, The Library of Congress, July 27, 2004, http://www.policyarchive.org/handle/10207/bitstreams/2137.pdf (Accessed 7/2/12); "Limitation on certain physician referrals" 42 U.S.C. §1395nn (2013).
16 42 U.S.C. §1395nn (2013).
17 "Health Care Fraud and Abuse: Practical Perspectives" By Linda A. Baumann, Health Law Section of the American Bar Association, Washington, DC: BNA Books, 2002, p. 106.
18 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule" Federal Register, Vol. 80, No. 220 (November 16, 2015), p. 71303.
19 *Ibid*, p. 71303-71306.
20 "Limitation on certain physician referrals" 42 U.S.C. § 1395nn(d)(2) (2018).
21 "Executive Order Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal" The White House, January 20, 2017, Federal Register, Vol. 82, No. 14, p. 8351-8352.

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