EVERSHEDS SUTHERLAND

PRIVILEGED AND CONFIDENTIAL
ADVICE OF COUNSEL

Memo

TO: Lever Stewart

FROM: Katherine Meyers Cohen

cc: Wade H. Stribling
Michael Gurion

DATE: April 16, 2018

RE: Regulatory issues raised by requiring additional provider credentialing

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I. Background

You have requested that we provide an opinion on a number of issues related to the additional credentialing Accushield provides to senior living communities and others. Accushield has an agreement with a number of senior living communities to provide an electronic kiosk or sign-in and to credential every person, other than personal guests of residents, who is allowed beyond the front desk in any participating community. Accushield also requires updated tuberculosis and immunization information on vendor employees which is particularly important for a population often more vulnerable to infection because of age. This provides an increased level of physical and medical security for the residents as well as the community as a whole. Accushield charges communities for installation and maintenance of each kiosk and charges vendors and providers for the work of the initial credentialing and updating background checks. Vendors and providers who wish to have their employees, contractors or agents allowed beyond the facility's or community's check-in point are required to have everyone who will have such access credentialed. We understand that this additional credentialing has not been welcomed by certain vendors. Therefore, we have reviewed Accushield's credentialing looking at three potential issues: fraud and abuse, possible prohibitions in Medicare and Medicaid, and protecting residents' rights and personal health information.

II. Fraud and Abuse

Fraud and abuse is the general term for violations of the Anti-Kickback Statute (AKS) and the prohibition on payment for physician referrals ("Stark"). The AKS prohibits offering, soliciting, paying or accepting payment, in cash or in kind, for any service or product which may be paid for in whole or in part by any federal or state health care program, the focus being Medicare and Medicaid. 42 U.S.C. § 1320-7a (civil penalties) and § 1320-7b (criminal

penalties). While it is possible someone could allege this practice falls into the category of fraud and abuse, it would be unlikely that charging for credentialing would be considered a kickback. Accushield's agreement is with the various senior living communities. The relevant provisions of those agreements require Accushield to provide electronic kiosks for sign-in by anyone entering a participating facility or community. If the individual signing into the kiosk has not been credentialed by Accushield, he or she will not be able to go beyond the check-in point, except in certain emergency situations.

In this case, to find a kickback, there must be an offer, solicitation, payment or acceptance of remuneration for products or services, in cash or in kind, directly or indirectly, made in order to obtain reimbursement that may be paid in whole or in part by federal or state health care programs. First, the payment is for an actual service being rendered to the facility or community. And it is not redundant because Medicare and Medicaid do not require credentialing of all employees of participating vendors, only owners, boards of directors, and key employees. They do not look at other employees. Second, additional credentialing beyond what is required by Medicare, Medicaid, or other programs is not a reimbursable expense. There is an ongoing cost to Accushield for maintaining updated credentialing and making certain that the employee who delivers services one month is the same as the individual who delivered services the previous month or that a new employee has been credentialed by Accushield. As long as it is not applied in a discriminatory manner, there is nothing we have found that would indicate this practice would be considered a kickback or bribe of any type.

It is possible to make the argument that vendors are paying for access, so-called "pay for play". The payment vendors make is for actual services being provided which have a cost attached to them. Those services provide a meaningful benefit to community residents. Some vendors may attempt to pass all or part of the charge for credentialing along to residents. That is a business decision for a vendor and is based on how large a profit the vendor wants to make for the services or supplies being provided. Residents and patients, in fact, make decisions all the time about which vendor to use based on cost. As long as there are vendors who do not charge residents, charge only part of the credentialing cost, or the increased charge is not sufficient to prevent the resident from being able to purchase the needed service or supply or make that purchase a hardship, there should be no deprivation of rights.

You should know that we have found no cases or advisory opinions indicating that this type of credentialing would violate the provisions of the AKS. It is our opinion that, as long as participating communities wish to require additional credentialing, the fact that Accushield charges for that process does not make the credentialing a violation of the AKS.

With respect to Stark, for there to be a violation of the statute and regulations, there must be a physician referral for designated health services. 42 U.S.C. §

1395nn. There is no such referral and no compensation so Stark should not be implicated.

III. Federal and state position on requiring additional credentialing for providers and vendors already credentialed by a federal or state program

We reviewed Medicare and Medicaid program participation requirements for providers and vendors. There is nothing of which we are aware that would prohibit requiring additional credentialing.

A. Medicare

As part of our research into whether there is anything at the federal or state level that would prohibit the additional credentialing provided by Accushield, we looked at relevant statutes and regulations and also reviewed a number of program materials and have spoken with multiple individuals in federal and state programs. In considering where such prohibitions might lie, we reviewed the participation requirements for nursing homes, assisted living facilities, personal care homes and the general requirements relating to all long term care facilities. We have found nothing that would limit the additional credentialing that Accushield provides.

Medicare has agreements with nine independent accrediting agencies (AO's) which are authorized to accredit facilities that want to participate in Medicare. We discussed the issue of requiring additional credentialing and charging for it with Ms. Kathleen Pankau, Senior Legal Counsel at the Joint Commission, the best known of the AO's. Ms. Pankau stated that requiring such credentialing of all vendor or supplier employees who go beyond the check-in point of a facility or community would not be a problem for the Joint Commission. She stated that she could not imagine any regulatory authority objecting to a facility's imposing additional credentialing requirements for the purpose of protecting patients and residents.

We also reviewed a number of other Medicare requirements, including but not limited to the following: (1) DME MAC Jurisdiction C Supplier Manual which covers Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, the US Virgin Islands, Virginia and West Virginia; (2) the Medicare DMEPOS Supplier Participation Agreement (CMS 460), and (3) applicable sections of the CMS Manual System. Additionally, we reviewed the Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Supplier Standards as listed in 42 C.F.R. §424.57(c). The responsibility for making certain that an individual applicant, such as a DMEPOS vendor, has met all required standards rests with Palmetto GBA which operates the National Supplier Clearinghouse. We reviewed the online

applications that vendors and suppliers complete. Not finding anything in these enrollment applications that would prohibit additional credentialing of DME employees, we contacted both the National Supplier Clearinghouse and Palmetto GBA directly. Neither saw any reason why a facility could not require additional credentialing as long as it is the facility's standard practice.

We have also discussed the issue of requiring additional credentialing with individuals at the Center for Medicare and Medicaid Services ("CMS"). The Medicare program sets out credentialing requirements and the forms which must be submitted as part of the credentialing process. Those forms do not require submission of the names of other than key employees, owners and directors. Therefore we contacted Linda D. Smith, the Associate Regional Administrator for the Division of Survey and Certification, for the Department of Health and Human Services ("HHS") Region IV which includes Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina and Tennessee. Ms. Smith's responsibility includes certification of Medicare providers and suppliers, including provider quality assurance. Other than accreditation of facilities, called institutional providers, by one of the AO's or through the enrollment process for others operated by Palmetto GBA, CMS leaves credentialing to the states. Most recently, because Ms. Smith is not directly involved with facilities, we discussed credentialing with Ms. Adriene J. Saunders, Health Quality Review Specialist, Centers for Medicare and Medicaid Services, Region IV-Atlanta whom Ms. Smith asked to respond on whether a Medicare enrolled facility could require additional and continuing credentialing of vendors and suppliers and their personnel. According to Ms. Saunders, the only restriction in terms of credentialing would be that a facility may not credential residents' visitors.

B. Medicaid

We also asked Ms. Smith and Mr. Gil Silva, the Deputy Regional Administrator for Region IV based in Atlanta (the Regional Administrator is in Dallas) whether there was an individual on whom they would rely for state credentialing issues. Each gave me the same answer: Ms. Nicole Thompson, who is Director of Provider Enrollment for the Georgia Department of Community Health (DCH), the Georgia state agency with responsibility for Medicaid and related programs. We discussed the issue of requiring additional credentialing under Medicaid. Ms. Thompson stated that the general facility and institutional provider agreements with Medicaid state that a facility may require additional or more stringent credentialing. We also reviewed the Georgia Medicaid standard contractors agreement. This agreement is with care management organizations (CMO's), not individual facilities. CMO's undertake credentialing and quality assurance, among other areas, on behalf of the state Medicaid program. The contract includes a provision that a CMO may require "more stringent credentialing than the State requires." Georgia CMO Agreement, section 4.8.15.1. GDCH, Provider Enrollment and Credentialing (August 27,

2014), p. 7. According to Ms. Thompson, Georgia Medicaid applauds any facility which does require additional credentialing. We discussed requiring separate credentialing for any employee, contractor or agent of a provider or vendor who was to be allowed beyond the facility check-in point. Ms. Thompson stated that there was nothing in the Medicaid provisions that would prohibit such credentialing. She also stated she thought it was a great idea and encouraged all facilities to take greater responsibility for credentialing those entering their premises. Like Medicare, Medicaid does not require credentialing of employees without substantial responsibility and CMO's only re-credential every three years, although they do annual inspections. O.C.G.A. §26-4-51(d).

IV. Additional Potential Issues

Could a vendor claim that the credentialing that Accushield is providing to facilities is redundant and therefore illegal? In our opinion, the answer is no because neither Medicare nor Medicaid require credentialing of all employees. The additional credentialing required by Accushield's facilities is of employees or contractors of vendors, suppliers and allied health providers who are allowed to go beyond the check-in point of a facility or community. Medicare and Medicaid have no idea of the identity of a vendor's delivery or other employees unless these individuals are considered key employees. Therefore, neither the credentialing nor the charge is redundant.

Is there a deprivation of rights for patients or residents? The answer seems to be no because there is no right to choose a particular provider or supplier. Where a community's or facility's residential contracts provide that vendors will be credentialed by the community or facility, residents are on notice and presumably have made a decision that this is a benefit they want. This answer may be qualified in a limited manner where a state strictly limits the entities or individuals providing a particular supply or service in the specific area. Where a state highly regulates a particular product or service and there are only one or two providers a community or facility may choose to accept Medicare or Medicaid credentialing. First, the type of provider is more highly regulated and therefore presumably more reliable and, second, the community does not want to deprive a resident of a needed service or supply. Any decision of this nature should be documented to protect the community and Accushield from an accusation of discrimination – accepting Medicare and Medicaid credentialing for some providers but not for others.

Communities have a responsibility and an obligation to protect their residents. Seniors as a class are a vulnerable population. It is right to impose a higher standard when dealing with a vulnerable population. And, it is a benefit to residents that communities are accepting a greater obligation because of their population. The legal community is beginning to see lawsuits brought for insufficient lighting of parking lots and common areas as a proximate cause of attacks on residents in residential complexes and customers at shopping malls.

While at this time there is insufficient evidence as to how far this theory of liability may be carried and how successful it will be nationally, it is not particularly speculative to state that attempts to impose liability will increase. Therefore, these issues are most important where employees or contractors of providers and suppliers could have contact with residents who are part of a vulnerable population. We note the same reasoning applies to and benefits community employees by providing a safer work environment.

If you have any questions or if we may be of assistance in any way, please do not hesitate to contact us.

K.M.C.