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Conditions of Participation

CMS rules do not preempt state delegation laws

In previous articles of *CMA Today*, I have attempted to demonstrate that the *Standards for Ambulatory Care*¹ and the *Comprehensive Accreditation Manual for Hospitals*² of The Joint Commission do not supersede state laws delineating medical assisting scope of practice. The purpose of this article is to provide evidence that the Centers for Medicare & Medicaid Services (CMS) Conditions of Participation (CoPs) also do not preempt or override state scope of practice laws. Specifically, I will argue that state laws regarding provider delegation to medical assistants are not altered or nullified when medical offices and clinics are owned, operated, or on the premises of a hospital that is required to meet CMS CoPs.

Conditions of Participation promulgated by CMS are mandatory measures, directly or indirectly addressing patient safety and well-being, that must be met by health care entities to participate in the Medicare and Medicaid programs

and receive reimbursement. The CoPs are codified in the *Federal Register* and are considered federal regulations. I will discuss the CMS CoPs for hospitals.

One of the CoPs for hospitals is the following:

42 CFR 482.23(c) Standard: Preparation and administration of drugs.

(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.³

A suggested interpretation of 482.23(c)(2) is that only nurses or other licensed health care professionals are permitted to administer “drugs and biologicals” in a medical office or clinic owned, operated, or on the premises of a hospital. It is my legal opinion that this interpretation is incorrect.

Note the following language from 482.23(c)(2):

All drugs and biologicals must be administered ... in accordance with Federal and State laws and regulations, including *applicable* licensing requirements.³ [Emphasis added.]

This regulation is saying that if federal or state laws include licensing requirements for certain categories of “other personnel,” then licensing requirements are “applicable” and individuals in these categories must meet such requirements to be delegated the administration of drugs. If there are no licensing requirements for a certain category of “other personnel,” the only requirement of 482.23(c)(2) is that the delegation of drugs and biologicals to individuals in this unlicensed category be permitted by federal and state laws.

It is also necessary to consider the language of 42 CFR 482.12(c)(1), which is another hospital Condition of Participation:

(1) Every Medicare patient is under the care of:

(i) A doctor of medicine or osteopathy (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under *State law or a State's regulatory mechanism*.);⁴ [emphasis added.]

Although 482.12(c)(1)(i) is a federal regulation, note that its language defers to state scope of practice laws for “other qualified health care personnel,” which would include medical assistants. According to this CoP, allopathic and osteopathic physicians are permitted “to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State’s regulatory mechanism.” In other words, if the laws of a particular state allow MDs and DOs to delegate tasks

to certain categories of “other qualified health care personnel,” this CoP does not interfere with the legal authority of allopathic and osteopathic physicians to do so. CMS does not limit delegation to only those “other qualified health care personnel” who are licensed. Rather, CMS allows delegation to “other qualified health care personnel” in accordance with the provisions of state laws.

If a state requires a certain category of “other qualified health care personnel” to be licensed, then physicians are permitted to delegate only to licensees in that particular category. If a state does not require a certain category of “other qualified health care personnel” to be licensed, then physicians are permitted

to delegate to unlicensed individuals in that category in the manner and to the extent that state law allows. ♦

Questions on how the Medicare and Medicaid Conditions of Participation interface with state law may be directed to CEO and Legal Counsel Donald A. Balasa, JD, MBA, at dbalasa@aama-ntl.org or 800/228-2262.

References

1. The Joint Commission. *2014 Standards for Ambulatory Care*. Oakbrook Terrace, IL: Joint Commission Resources; 2014.
2. The Joint Commission. *Comprehensive Accreditation Manual for Hospitals*. Oakbrook Terrace, IL: Joint Commission Resources; 2016.
3. 42 CFR §482.23 (2018).
4. 42 CFR §482.12 (2018).

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