

The Physician's Checklist for Starting a Direct Primary Care Practice

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Direct primary care practices have received considerable attention lately, so it seems timely to discuss some of the legal and regulatory challenges facing physicians who wants to establish their very own direct primary care practice. Frost Brown Todd's Health Care Innovation Team and have advised physicians interested in these direct primary care models, and I encourage any physician interested in learning more to contact me to get started. Below is a checklist of some of the items physicians should consider when starting their own direct primary care practice.

1. State Laws and Regulations on Direct Primary Care Practices.

Some states have passed legislation to address direct primary care practices after they began to gain popularity. One of the main drivers of this type of legislation was ensuring that consumers would not think the direct primary care model was a form of insurance. Therefore, any physician who plans to engage in this model of delivering medical services must check state laws and regulations to ensure compliance with any applicable requirements. For example, Indiana passed legislation in 2017 with certain requirements for direct primary care practices (Indiana Code 25-1-10 et seq.). Indiana's Code provides that direct primary care agreements are not the business of insurance, and it also requires that any direct primary care agreements between physicians and patients must prominently state in writing that the agreement "is not health insurance."

2. Legal Entity Formation.

Forming a legal entity is important when it comes to starting a direct primary care practice because it helps shield the physician from personal liability associated with the practice. Many physicians setting out on their own with a direct primary care practice will likely choose to form a limited liability company (LLC) over a

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corporation based on the LLC's flexible governance structure. Furthermore, limited liability companies with a single owner can be "disregarded" for federal income tax purposes, which means all taxes from the direct primary care business are reported on the physician-owner's personal tax return which avoids double-taxation issues associated with being taxed as a corporation.

However, one issue physicians also needs to consider before forming a legal entity is whether the state in which they intend to provide medical services has a prohibition on the corporate practice of medicine, which may require them to form a professional corporation or "P.C.," as opposed to a different legal entity like a corporation or a limited liability company. State laws often specify how professional corporations must be structured, who can participate as shareholders or owners, and who must serve on the board of directors. Most states restrict the shareholders, owners, or board of directors of a professional corporation to persons licensed to render the professional service being offered by the professional corporation. These prohibitions on the corporate practice of medicine came from concerns related to commercialized medicine, including whether a corporation's obligations to its shareholders to earn a profit would result in medical decision-making that is not based on the needs of the patient.

3. Medicare Opt-Out (if applicable).

Normally, a physician is required to submit claims on behalf of Medicare beneficiaries for all items and services provided for which Medicare payment may be made under Part B. Also, a physician is not allowed to charge Medicare beneficiaries in excess of the limits on charges that apply to the item or service being furnished. However, a physician may opt out of Medicare. A physician who opts out of Medicare is not required to submit claims on behalf of Medicare beneficiaries and is excluded from limits on charges for Medicare-covered services. Thus, physicians who plan to start a direct primary care practice will want to make sure they have properly opted-out of Medicare so they may enter into private agreements with Medicare beneficiaries to allow the physician to

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charge such beneficiaries directly for medical services at prices set by the physician.

4. Patient Agreement.

A patient agreement is needed to establish the legal bounds of a physician's relationship with patients. This is typically done through an agreement where the patient agrees to pay a periodic fee to have access to a physician's direct primary care practice for medical services. This agreement is critical because not only does it detail how payment works, but also it can establish other aspects of the physician-patient relationship like the specific types of services provided for the fee, other services the patient can purchase outside of the fee, the duration of the direct primary care relationship, and a disclaimer to the patient that no insurance is involved in the arrangement.

5. Privacy Issues.

Obviously, patient privacy remains paramount, whether a physician is employed with a large health system or has established her own direct primary care practice. The HIPAA Privacy Rule establishes a Federal floor of safeguards to protect the confidentiality of patient medical information; however, State laws that provide stronger privacy protections will continue to apply over and above the Federal privacy standards. Therefore, determining whether physicians are subject to HIPAA through their direct primary care practice is critical, and it is also important to know which state privacy laws may apply to the physician's practice.

Direct primary care practices continue to be another way in which physicians attempt to innovate and disrupt healthcare. Some physicians believe it gives them more control over their schedule and allows them to spend more time with their patients, as opposed to time spent on administrative tasks related to billing third-party payors.

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