

COMMENTS BY THE HEALTH LAW SECTION

Health #1

April 8, 2013

On behalf of the Health Law Section of the New York State Bar Association, we thank you for the opportunity to submit comments in response to the February 25, 2013 letter of Karen Lipson and Joan Cleary Miron.

1. **Question:** Should New York State expand or modify the criteria that define a DTC under 10 NYCRR § 600.8?

Answer: Yes, New York State should modify the criteria in § 600.8 for the reasons that follow.

We note, as a preliminary matter, that the licensure and regulation of physicians engaged in the private practice of medicine, whether in small groups or in complex multi-specialty mega-practices, is the purview of the Department of Education, not the Department of Health.¹ Thus, any attempt by the Department of Health (“DOH”) or the Public Health and Health Planning Council (“PHHPC”) to amend Title 10 of the NYCRR in order to bring any type of physician practice under the regulation of the Department of Health as a diagnostic and treatment center, and to subject it to Certificate of Need approval, would likely not survive the expected legal challenges to such an administrative action. We believe legislation would be necessary. See, e.g., *Boreali v. Axelrod*, 71 NY2d 1 (1987).²

¹ The PHHPC appears to be aware of this issue, since it states the following in an appendix to its recently adopted report on redesigning the CON process: “Notably, private physician practices are generally not covered by CON,” citing to *Clifton Springs Sanitarium Co, Inc v. Axelrod*, 115 A.D.2d 949 (1985). See PHHPC Report on Redesigning Certificate of Need and Health Planning adopted on 12/6/2012 at Appendix F, fn 2. Leave to appeal was denied, 67 N.Y.2d 609, 494 N.E.2d 114, 1986 N.Y. LEXIS 18174, 502 N.Y.S.2d 1028 (1986).

² In this connection, legislation was advanced by Governor Mario Cuomo in the early 1980s seeking to subject the acquisition of certain imaging equipment (such as CAT and MRI equipment) to CON review. That legislation was never enacted. The failure to enact that legislation could be used to support an argument that DOH lacks authority now to require a CON. Indeed, the court in *Clifton Springs* notes that “efforts in recent years to bring privately owned equipment used on hospital inpatients within the State’s CON requirements have consistently failed to obtain legislative approval.”

The purpose of § 600.8 is to define what constitutes a “facility or institution engaged principally in providing services by or under the supervision of a physician...” pursuant to Public Health Law § 2801(1) and to distinguish such a facility from the operation of a physician office. The former is subject to licensure and CON review by DOH, and the latter is not.

- The criteria currently listed in § 600.8 fail adequately to distinguish between the operation of a facility and the private practice of medicine. The current criteria are both over- and under- exclusive, and are outmoded. Examples follow:
 - § 600.8(a) only mentions one legal way to organize a group practice, as a professional service corporation (“PC”), and fails to mention other ways now legal under New York law, including as a professional limited liability company (“PLLC”) or a university faculty practice corporation (“UFPC”) organized under section 1412 of the Not-For-Profit Corporation Law.
 - § 600.8(c)(1) and (c)(4)(ii) and (v): In a large, multi-specialty group, a primary care physician may refer a patient for laboratory or radiology services to “another location” not in his office.
 - § 600.8(c)(3): In a large physician practice, the practice may allow “after hours” services, where a patient may end up seeing a physician that the group practice has assigned to see all patients of the group practice after regular office hours.
 - § 600.8(c)(4)(iii): In this day and age, a physician group practice often “insures adherence to standards” such as quality standards and other standards required by third party payors such as Medicare and MCOs.
 - § 600.8(c)(5):
 - Physician group practices enter into managed care contracts that require the group to determine the amounts to be billed. Payments generally are made to the group, not to the individual physician.
 - Given HIPAA requirements and laws and regulations governing electronic medical records, the group is responsible for maintaining medical records and patient charts.
 - Income distribution is a function of the partnership agreement, PLLC operating agreement or employment contract between the group and the physician.
 - The criteria fail to consider *control* by non-physicians through financing, administration, and management.
- The Department of Health (“DOH”) does not actively enforce the provisions of the current regulation. Having regulations that the state does not enforce undermines respect for the law. It also makes it difficult for attorneys to advise clients on properly structuring arrangements.

- Moreover, we are aware of instances in which DOH staff have advised entities that meet the criteria in section 600.8 not to seek licensure as a DTC, apparently because of the potential impact on Medicaid reimbursement. As we understand it, Medicaid reimbursement to a DTC for the facility fee under APGs, together with reimbursement for the professional services under the Medicaid fee schedule, is usually higher than fee-for-service reimbursement on a global basis to a site organized as a physician office . If it is not in the state's economic interest for a site to become a DTC due to the impact on Medicaid reimbursement, then DOH should consider deleting section 600.8 or modifying it (together with modifying the criteria for establishment and licensure of DTCs) to identify only those entities that DOH believes should be licensed as a DTC and should be reimbursed under APGs for ambulatory services to Medicaid patients. Alternatively, the state should consider modifying its Medicaid reimbursement regulations to provide the appropriate amount of reimbursement for ambulatory patients in each ambulatory setting. We recognize that the state has already made significant revisions in Medicaid reimbursement to ambulatory sites licensed under Article 28 in Part 86-8 of its regulations, and has also approved some increases to physician reimbursement to lessen the Medicaid differential between sites of service. We also understand that, as Medicaid fee-for-service patients transition to mandatory managed care, this difference in reimbursement may disappear, since many managed care companies pay the same amount to DTCs and to physician offices. Nonetheless, as long as Medicaid fee-for-service reimbursement continues to exist, this differential in payment will continue to exist, as well, creating an incentive for DOH staff (i) not to enforce § 600.8 and (ii) to discourage applicants who wish to become licensed as a DTC.

- In the event that physician acquisition or operation of major medical equipment were to be subject to CON review, it would be essential that the need methodologies for this equipment be thoroughly reviewed and substantially updated. To some extent, the need criteria take into account the existing physician resources. However, if physician practices were suddenly to be subject to CON review and if existing physician owned or leased equipment were counted in determining need under the existing need methodologies, the result could well be a determination that there is no need for any additional imaging equipment or linear accelerators—even though an aging population, at greater risk of cancer, may well require substantially more of such equipment. As a result, unless the need methodology is thoroughly revisited, the effect of expanding CON review for the operation of this equipment would be to enact a virtual moratorium on any new capacity, which would stymie both hospitals and physicians from meeting real unmet need.

For the reasons set forth above, we submit that DOH should significantly modify the criteria set forth in section 600.8 or delete this section of the regulations. In conjunction with deciding what criteria to use in a revised regulation, DOH should consider which

entities should be licensed or otherwise regulated under Article 28 of the Public Health Law. DOH should also consider the impact, if any, of Medicaid reimbursement methodologies on the position it takes as to which entities need to be licensed under Article 28 of the Public Health Law. Finally, if DOH expands CON review for any type of facility or equipment to physician practices, it should do so only after reviewing and revising the need methodology.

2. **Question:** Should New York State modify its approach to the corporate practice of medicine?

Answer: Yes, for the reasons that follow.

- While there are strong justifications for maintaining a corporate practice prohibition to assure that physicians and other licensed entities control medical service delivery,³ the existing prohibition on the “corporate practice of medicine” does not take into account the desirability of promoting certain healthcare delivery models. Indeed, this prohibition – if enforced – would hinder use of care delivery models that promote the Triple Aim. This prohibition also creates anomalies in the employment relationships that are allowed and disallowed under NY law, without promoting any legitimate public policy purposes for doing so. Examples follow.
 - o Taken to its logical extension, the “corporate practice of medicine” prohibition would bar a hospital from requiring its employed physicians to turn over all fees for professional services rendered at physician office sites that are not on the hospital’s operating certificate. This is because the hospital is not “licensed” to operate from these sites, and the prohibition is really a prohibition on the unlicensed practice of medicine by a corporation.⁴ The fact pattern noted above implicates not only the prohibition against the “corporate

³ Thus, we acknowledge that New York State has a legitimate interest in preventing corporations that have no license from any state agency to provide any type of healthcare from employing physicians and holding themselves out to the public as providing medical services.

⁴ The prohibition on the “corporate practice of medicine” is – in reality – a prohibition on the unlicensed practice of medicine. That is, it is a prohibition on the employment of physicians by a corporation that has no license issued by the state authorizing it, as part of its licensed duties, to employ physicians to provide healthcare services to the public. Thus, a series of cases interpret this prohibition as providing exceptions allowing corporations to employ physicians as long as the corporation has a license issued by the state that authorizes it to provide healthcare services to the public, such as a hospital or a medical school. See, e.g., *Albany Medical College v. McShane*, 104 AD2d 119, 481 NYS2d 591 (3d Dep’t. 1984); *aff’d* 66 NY2d 982, 199 NYS2d 376 (1985).

practice of medicine,” but also fee splitting and § 401.2(b) of the DOH regulations relating to operating certificates, which limits where the established operator may operate.⁵ See, e.g., *Glassman v. ProHealth Ambulatory Surgery Center*, 23 A.D.3d 522, 806 NYS2d 648 (App. Div. 2d Dept. 2005); rev’d on other grounds in 14 N.Y. 3d 898, 930 N.E.2d 263, 904 N.Y.S.2d 342 (2010). See fn. 7, *infra*. As we note below, in practice these restrictions are frequently disregarded and not enforced.

- In contrast, employed physicians of a medical school can be required to turn over all fees earned at all sites, even sites not on an operating certificate, since a medical school may employ physicians to work at any site pursuant to its faculty practice plan and its charter that allows training of residents. See, e.g., *Albany Medical College v. McShane*, 66 NY 2d 982, 489 NE2d 1278, 499 NYS2d 376 (1985).
- From a public policy perspective, it makes no sense to allow physicians who are employees of a medical school to have an unrestricted practice, but to place restrictions on the physician employees of a hospital.
- The irrationality of this outcome is underscored by the difference in treatment accorded to hospitals whose affiliated medical schools are in the same corporation, compared to those that are in separate corporations.
 - Where a hospital and a medical school are in the same corporate entity, the corporate practice of medicine doctrine, as applied, has allowed the entity to require employed physicians to turn over their income from all sites, even sites not on the hospital’s operating certificate.
 - However, where a hospital and a medical school are not in the same corporate entity, the corporate practice of medicine doctrine – together with section 401.2(b) of the Department’s regulations - bars the hospital from employing physicians to work at sites not on its operating certificate. It makes no sense for the law to have this anomalous outcome.
- Moreover, under the federal Antikickback and Stark laws, as well as their New York counterparts, the exceptions that apply to physicians who are employees of a hospital give greater flexibility in structuring compensation relationships than the exceptions that apply to physicians who are independent contractors. The state should not, through the “corporate practice of medicine” prohibition, discourage the employment of physicians by hospitals.

⁵ Section 401.2(b) provides: “An operating certificate shall be used only by the established operator for the designated site of operation, except that the commissioner may permit the established operator to operate at an alternate or additional site approved by the commissioner on a temporary basis in an emergency.”

- For example, many hospitals in New York have established so-called “Captive PCs” in order to structure relationships with physicians who practice at the hospital as well as at non-hospital sites.⁶ A Captive PC is a professional service corporation controlled indirectly by a hospital, with the shares in the PC held by a licensed physician who is employed by the hospital with a particular job title, and a shareholder’s agreement requiring that physician to relinquish the shares to the next holder of that title if he/she ever ceases to hold such title.
 - Under the Captive PC model, the PC employs the physicians. When the physicians are employees of the PC and not of the hospital, the hospital and the physicians do not have the benefit of the more flexible employment exception that exists under the federal Antikickback and Stark laws, as well as their state counterparts. Moreover, complex legal and business issues arise with respect to contractual relationships and the flow of funds between the hospital and the PC.
- In addition, the “corporate practice of medicine” prohibition creates legal issues when trying to structure a network of providers for purposes of contracting with self-insured employers. These networks *arrange* for the provision of medical services, which New York State defines as the practice of medicine. Moreover, an IPA cannot be used to contract with a self-insured employer, since that is not a purpose allowed under Part 98 of the DOH regulations.
 - New York State has rarely enforced the “corporate practice of medicine” prohibition, at least in recent years.
 - Instead, this prohibition appears most often to be raised by private litigants in the context of breach of contract lawsuits, where one party seeks to get out of its contractual obligations by claiming that the entire contract should be void as against public policy or that a particular provision should be severed as illegal. See, e.g., *Glassman v. ProHealth Ambulatory Surgery Center*, 23 A.D.3d 522, 806 NYS2d 648 (App. Div. 2d Dept. 2005); *rev’d* on other grounds 14 N.Y. 3d 898, 930 N.E.2d 263, 904 N.Y.S.2d 342 (2010).⁷

⁶ A physician group practice, whether formed as a PC, a professional limited liability company, or a partnership is permitted, by its license to practice anywhere in the state.

⁷ In reversing the appellate court’s holding, which had severed as illegal a provision in an employment contract between an ASC and a physician requiring the physician to turn over to the ASC all fees earned at non-ASC sites, the Court of Appeals did not hold that the contested contract provision was legal. Instead, the Court held that the provision was at most “merely *malum prohibitum* and, therefore, enforceable in a breach of contract action.” The court explained that DOH has authority to enforce the provisions of its regulations in section 401.2(b) that authorize an Article 28 facility to operate only from sites on its operating certificate, and that OPMC has authority to enforce fee splitting violations. It also noted that the plaintiff had not “identified an overarching public policy that mandates voiding the contract.” 14 N.Y. 3d 898, 930 N.E.2d 263, 904 N.Y.S.2d 342 (2010).

- Applying this prohibition to hospitals and to networks of providers contracting with self-insured employers, while not enforcing it, creates impediments for law abiding citizens and facilities who are trying to structure legally binding arrangements. This is particularly the case here, since the penalties include criminal penalties. The unlicensed practice of medicine, as well as abetting the unlicensed practice of medicine, are Class E felonies. Ed. L. § 6512.⁸
- As we noted above, in discussing section 600.8, the failure to enforce a law promotes disrespect for the law. If the state is not going to enforce the “corporate practice of medicine” prohibition, it should eliminate it. Of course, this will likely require legislation.⁹
- **Other Licensed Professionals:** If the state eliminates or modifies the prohibition on the “corporate practice of medicine,” it should also consider eliminating or modifying this prohibition as it applies to other licensed health professions.
- **Fee Splitting:** The state should also consider modifying the prohibition against fee splitting to take account of the current and proposed models of health care delivery that are designed to achieve the Triple Aim. The facts that support a charge of violating the “corporate practice of medicine” usually also implicate the prohibition against “fee splitting.” Therefore, if you address one prohibition, we suggest that you also consider addressing the other, as well.¹⁰

Other Observations:

Finally, we share the Department’s concern about the lack of access to capital by New York hospitals. We note that this problem would potentially be exacerbated if the Department were to relax the prohibition on the corporate practice of medicine by entities not licensed under Article 28 of the Public Health Law (thereby, in effect, allowing physicians access to capital), while at the same time retaining (rather than relaxing) the

⁸ Moreover, willfully violating § 401.2(b) of the DOH regulations is a misdemeanor, with a potential sanction of one (1) year in jail effective 4/1/2014. See Public Health Law § 12-b.

⁹ However, if DOH were to revise its regulations in section 401.2(b) to authorize a hospital to employ physicians to work at a site not on the hospital’s operating certificate so long as the services are not billed as hospital outpatient services (and instead are billed as physician office services), this might obviate the need for legislation.

¹⁰ In this connection, we are pleased that the PHHPC has recommended “relax[ing] the prohibition on revenue sharing among providers that are not established as co-operators” presently prohibited by section 600.9, which is sometimes referred to as “corporate fee-splitting.” See Recommendation #22 of the PHHPC Report on Redesigning Certificate of Need and Health Planning, adopted 12/6/2012 at p. 46.

CON restrictions applicable to entities licensed under Article 28. We respectfully request that you keep this in mind as you consider potential regulatory and legislative changes.

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