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VIA HAND DELIVERY

Joseph. F. Vitale
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Re: S2724: Requires alternative payment models to register with DOH; permits health care practitioners to refer patients to health care service in which the practitioner has beneficial interest when related to alternative payment model

Dear Chairman Vitale:

I am writing to you in my capacity as President and Chairman of the Board of Directors of the New Jersey Patient Care and Access Coalition ("NJPCAC") in support of S2724. Twenty-five years ago, the New Jersey Legislature—with Governor Codey as principal sponsor—passed a self-referral law that has been an important part of our State's health care policy for more than a generation. In a strictly fee-for-service payment system, the law struck an important balance between preserving patient access to high quality health care and maintaining safeguards against the potential for over-utilization of health care services. The law—known as the Codey Act—remains a critical piece of New Jersey's health care policy, but it is in need of important, limited changes that will modernize the statute to account for our shift away from fee-for-service medicine to value-based care. We are thankful to Governor Codey and you, Chairman Vitale, for proposing these limited reforms in S2724 and for your leadership in holding a hearing on S2724.

As you know, the way healthcare is delivered and financed in New Jersey has undergone significant change in recent years. The federal government has imposed new statutory and regulatory requirements, private payers are developing innovative new models to pay for healthcare, and physicians and other practitioners continue to work to improve patient outcomes. But in some important ways our state law has not evolved as quickly as federal law to help patients and practitioners navigate these changes. In some cases, this mismatch between state law and federal requirements can create barriers that prevent physicians and other healthcare practitioners from working together to deliver the highest-quality, most efficient care to their patients.

NJPCAC supports S2724 because this bill will modernize the Codey Act to address these barriers while preserving all key components of the Act's existing structure.

Limited revisions to the Codey Act are necessary because of the unprecedented changes in the way healthcare providers are paid under the Affordable Care Act, other federal laws, and new kinds of private payer models.

- The Codey Act is directly modeled on the federal Physician Self-Referral Law (the "Stark Law"). But, while the federal government has issued many waivers of the Stark Law to facilitate major changes to Medicare reimbursement, **no such waivers or exceptions are currently authorized under the Codey Act.**

- The Stark Law and Codey Act are both designed to prevent potentially improper financial relationships in a **fee-for-service** environment, where healthcare providers receive more payment for performing more services. But this payment model is becoming less common; the Centers for Medicare and Medicaid Services ("CMS") has committed to basing 90% of Medicare payments on objective measures of **quality** (rather than volume) by 2018, and to making 50% of Medicare payments through **new "Alternative Payment Models"** by 2018.

- The Affordable Care Act and the bipartisan Medicare Access and CHIP Reauthorization Act ("MACRA") authorize new voluntary and mandatory Medicare and Medicaid Alternative Payment Models, and encourage private payors to develop similar models. **New Jersey providers cannot fully participate in these new models without flexibility similar to the kind provided under federal law.**

New Jersey now has an opportunity to use the substantial work done by the federal government in order to implement similar kinds of flexibility here in our State while preserving the Codey Act's key protections. S2724 adapts the core concepts of federal Stark Law waivers to the Codey Act to allow new opportunities for practitioners to work together collaboratively to transform health care delivery.

The New Jersey Patient Care and Access Coalition

NJPCAC is a physician-driven advocacy coalition focused on addressing the challenges facing our State's health care system and ensuring that our patients continue to receive the highest quality specialty care. Our mission is to promote and protect the high quality, cost-efficient and comprehensive care furnished by independent medical practices to patients in New Jersey. NJPCAC's membership of independent medical practices includes more than 200 physicians across various specialties who care each year for approximately 500,000 patients in more than 50 towns across New Jersey. Our membership also includes the Stone Center of New Jersey, one of the largest lithotripsy facilities in the country. Since its inception in 2008, NJPCAC's physician members have come together to educate policy makers, regulators, insurers, and other key stakeholders about legislative and regulatory changes that affect access to and the delivery of health care in New Jersey.

The Codey Act Can Limit Value-Based Care Models

The Codey Act was enacted in 1991 to address concerns of potential over-utilization or improper utilization of health care services.[i] The Act prohibits health care practitioners (including physicians) from referring patients to a "health care service," if the practitioner has a "significant beneficial interest" in or with that health care service. A "health care service" is "a business entity which provides on an inpatient or outpatient basis: testing for or diagnosis or treatment of human disease or dysfunction; or dispensing of drugs or medical devices for the treatment of human disease or dysfunction."[ii] These "health care services" include various provider entities such as hospitals, pharmacies, and skilled nursing facilities. A "significant beneficial interest" means any financial interest, whether in the form of ownership or compensation.[iii] If a health care practitioner violates the Codey Act, payment for these referred services is subject to recoupment, and the practitioner may be subject to significant penalties.[iv] These definitions are in fact much broader than the federal Stark Law, as they implicate reimbursement from *all* payers (not just Medicare), are not restricted to "designated health services," and treat *any* kind of financial relationship as a potential "significant beneficial interest." As we move to a health care payment structure that incentivizes care coordination across health care entities, the breadth of the Codey Act's prohibitions may impede efforts to coordinate care between practitioners and other kinds of health care entities.

Although the Codey Act has a number of exceptions, none addresses the modern challenge of implementing Alternative Payment Models. For example, the Codey Act includes an exception from the general prohibition on referrals for medical treatment and procedures provided at the practitioner's medical office and for which a bill is issued directly in the name of the practitioner or the practitioner's medical office.[v] However, this exception does not cover contractual relationships between independent entities that seek to participate jointly in new care models. As a result, the structure of the Codey Act unintentionally fosters "siloed" care in which providers enjoy far broader legal protection if they avoid working together with other entities involved in a patient's care. In marked contrast to the federal Stark Law that served as the model for the Codey Act, there are no specific exceptions, waivers, or other flexibility within the Codey Act to support the value-based care models that are being created under the bi-partisan Medicare Access and CHIP Reauthorization Act ("MACRA") enacted by Congress in 2015.

As a concrete example of the impediments created by the Codey Act, consider one of the most common Alternative Payment Models: a "bundled payment" system.[vi] Under this kind of payment model, a payer sets a single benchmark price for all of the elements of treating a given medical condition—whether in the hospital, physician office, ambulatory surgical, or post-acute setting. The participants in a bundled payment program then receive a bonus (or are assessed a penalty), based on whether or not the cost of the patient's care *in all settings* is greater or less than the benchmark. Success under this model therefore requires health care practitioners and health care services to share information, resources, data analytics, and personnel to improve their management of a patient's care. In addition, each practitioner and health care service has a new financial incentive to provide high-quality care using the most efficient treatment methods and/or sites of service. Many kinds of resource-sharing used to change the way care is delivered to achieve these efficiencies in care delivery may constitute "significant beneficial

interests" under the Codey Act. And, depending upon the parties involved, this kind of arrangement may be unable to fit an existing Codey Act exception.

Although these value-based payment models are complex, they are becoming increasingly common. For example, MACRA brings this kind of "episode-based" analysis into the heart of Medicare reimbursement. As a result, health care practitioners such as physicians face special urgency to find ways to work together under federal law. The Codey Act needs to be modernized much like the federal law was last year to ensure that our state self-referral law does not become an unintentional barrier to collaboration among independent healthcare entities.

Major Changes in Federal Requirements for New Jersey Providers

The current rigidity of the Codey Act for independent contractor arrangements is particularly concerning, since the federal government is moving so aggressively to embrace value-based care. This trend began with the Affordable Care Act, which created a voluntary Accountable Care Organization ("ACO") program, and a new department of CMS called the Center for Medicare and Medicaid Innovation ("CMMI"). These initiatives use the enormous lever of Medicare payments to change the way that healthcare providers deliver care. As a result, it is important to understand how they impact providers in New Jersey, who may have difficulty participating in these initiatives without limited updates to the Codey Act.

In an ACO, providers (often in different legal entities) work together to manage the cost and healthcare quality of a wide-ranging Medicare patient population. If the participants in an ACO are able to maintain high quality care while reducing overall Medicare costs, the participants in the ACO may share a portion of the Medicare program's savings. In some advanced ACO models, participants can earn higher bonuses by accepting the "downside risk" of financial losses. ACOs are currently the most common form of Advanced Payment Models, and S2724 incorporates elements of this model into state law.

CMMI has developed its own set of more advanced ACOs, as well as a number of other models. Since its inception in 2011, CMMI has released dozens of Alternative Payment Models, virtually all of which pay health care providers on the basis of the collective value they provide. Unfortunately, many of these models raise concerns under the Codey Act's referral prohibitions if distinct entities collaborate to achieve their goals.

This spirit of innovation and delivery system transformation is not limited to the Medicare program. Private payers and employers across the nation are adopting similar strategies. Here in New Jersey, private payers have already developed their own versions of private Accountable Care Organizations and similar models, based in large part on CMS models.[vii] Physicians must increasingly consider these kinds of new models as they manage their practices and serve the widest set of patients.

Although these models began on a voluntary basis, the federal government is increasingly requiring providers to participate. The bipartisan MACRA legislation will base *all* Medicare professional reimbursement, in part, on quality and cost metrics. Under MACRA, physicians who participate in formal "Alternative Payment Models," will receive significant Medicare

payment bonuses. At the same time, in the last year, CMMI has proposed or enacted many forms of mandatory specialty-specific value-based payment programs, including programs covering knee replacements, cardiology services, and certain kinds of physician-administered drugs.

In short, New Jersey physicians and other practitioners need the limited reforms set forth in S2724 to ensure that they can work together—across sites of service—to furnish coordinated, cost-efficient and high quality care.

Changes to the Stark Law – Model for the Codey Act

Like the Codey Act, the Stark Law was passed a generation ago. The basic structure of the Codey Act was designed to mirror the Stark Law. However, in recent years—following passage of the Affordable Care Act—the federal Stark Law has been modified substantially. CMS has created many new regulatory exceptions and implemented new waivers to the federal law that are specifically designed to facilitate a shift to value-based care. For example, under CMS regulations, exceptions exist for risk-sharing arrangements, fair-market value compensation arrangements, and other arrangements that are common in value-based care models.[viii]

Perhaps most importantly, the Affordable Care Act explicitly authorized waivers of Medicare rules (including the Stark Law) if necessary to implement ACOs and CMMI models. CMS has repeatedly found that waivers of the Stark Law were, in fact, necessary.[ix] As a result, CMS has issued many new waivers designed to protect parties who were working together in an ACO or another formal value-based care relationship.[x] The structure of S2724 is modeled after the most flexible of these waivers, which applies to the Medicare Shared Savings Program (the most common ACO program).

The Codey Act Should be Modernized to Support Delivery System Reform

S2724 is directly based on efforts by Congress and CMS to facilitate value-based care. As stated above, it adopts the MACRA legislation's framework for regulating Alternative Payment Models as well as the provisions of the Stark Law's waiver for ACOs. Specifically, the bill creates a process for participants in an Alternative Payment Model to protect certain referrals that would otherwise violate the Codey Act, so long as the referrals and related financial arrangements meet certain standards. This is a limited exception; potential participants in an Alternative Payment Model would be required to submit an application to the Department of Health describing the participants in the model, and the ways in which the model would meet patient-centered goals.

S2724 sets out specific standards for an Alternative Payment Model, which are based directly on the requirements of MACRA. An Alternative Payment Model means a model of payment for health care services operated by Medicare, Medicaid, or a health insurance carrier that: 1) has been filed with the Department of Health; 2) provides for payment for covered professional services earned by participating health care practitioners and health care services based on approved quality measures; and 3) fits into a specific class of value-based payment models. The Alternative Payment Model must either be an ACO authorized under relevant CMS rules,

be a medical home, or must require an "Alternative Payment Entity" to bear financial risk for monetary losses.

The new exception created by S2724 retains the structure of the Codey Act while creating certain limited, new flexibility for participants in Alternative Payment Models. Under S. 2724, the Department of Health will review applications for new Alternative Payment Models. S2724 lists the mandatory elements for such an application. Prospective participants must disclose substantial information to the Department including a list of all participants, a statement regarding the Alternative Payment Model's compliance with applicable New Jersey law, a description of the organizational structure and the role of each participant, and any other information requested by the Department of Health. Importantly, S2724 mandates that an Alternative Payment Model must meet certain defined standards: "institutional and specialty-specific goals under an Alternative Payment Model related to patient safety, use of Approved Quality Measures and any other applicable quality of care goals, and operational performance, which may incorporate specific patient management tasks, care redesign initiatives, and patient safety and quality of care objectives." The Department is responsible for reviewing the relevant applications and requesting any additional information to determine whether the Alternative Payment Model meets these standards. Unless the Department issues a notice of rejection within sixty days, the Alternative Payment Model may go forward.

S2724 also adapts the existing federal process used for waivers of the Stark Law for Accountable Care Organizations, under which participants must follow defined rules to protect specific kinds of significant beneficial interests. This process has the advantage of protecting a wide variety of significant beneficial interests while avoiding rigid, pre-defined standards that may become out-of-date as the healthcare industry continues to evolve.

Once an Alternative Payment Model has been approved by the Department, participants in that model could choose to waive the application of the Codey Act's referral prohibition as it applies to certain specific significant beneficial interests. The participants would be required to make a written determination that clearly identifies the applicable significant beneficial interest and identifies how waiving the Codey Act would contribute to an Alternative Payment Model standard. This process will ensure that any waiver is directly tied to the overall goals of the program. The Alternative Payment Model participants would be required to maintain these written determinations and disclose them to the Department of Health and enforcement bodies upon request. The Department would therefore be empowered to monitor the use and application of this waiver power over time.

S2724, therefore, takes an existing federal waiver model that has been in place for Accountable Care Organizations (the most common type of federal Alternative Payment Model) for many years and adopts it to the unique needs of New Jersey. This policy has the advantage of using a set of processes to protect novel financial arrangements that many healthcare providers already understand, while giving the Department of Health meaningful oversight powers to regulate these processes. We believe this limited change to modernize the Codey Act will have significant benefits for New Jersey physicians and other practitioners and the patients for whom they care.

S2724 Is One Part of a Wider Effort to Modernize the Codey Act

S2724 creates a flexible framework that can be used by a wide variety of practitioners who seek to align to deliver high quality, cost-efficient care in various ways. For example, this approach would allow a primary care practice, specialty practice, and skilled nursing facility to participate in a bundled payment program without creating an impermissible "significant beneficial interest" between them. However, S2724 does not preclude other changes to the Codey Act. For example, we know that this Committee is also considering S913, which would create an exception within the Codey Act to protect significant beneficial interests under a "hospital and physician incentive plan." That bill, along with S2724, are efforts designed to modernize the Codey Act and we do not believe that there is anything in either bill that would preclude this Committee moving forward on both pieces of legislation. Because S2724 will enable health care practitioners and health care services to implement new strategies to improve care, regardless of the site of service, we believe that any comprehensive strategy to modernize the law needs to include S2724.

In closing, we appreciate the opportunity to work with you and the Committee to modernize the Codey Act. The limited exception contained in S2724 will update the Codey Act to reflect the modern state of healthcare delivery in 2016, while preserving the critical protections of the Codey Act that have been in place for the last 25 years. The limited changes to the Codey Act set forth in S2724 will enable physicians and other practitioners across medical settings to work collaboratively to bring the most innovative, high-quality, and cost-efficient health care to New Jersey patients.

Sincerely,

Alan Krieger, M.D.
Chairman of the Board & President, NJPCAC

cc: All Members of the Senate Health, Human Services and Senior Citizens Committee

[i] N.J.S.A. 45:9-22.4 *et seq*.
[ii] N.J.S.A. 45:9-22.4
[iii] Id. See also N.J.A.C. 13:35-6.17.
[iv] N.J.S.A. 45:9-22.8, citing N.J.S.A. 45:1-25.
[v] N.J.S.A. 45:9-22.7
[vi] See e.g., Joel V. Brill, et al., "A Bundled Payment Framework for Colonoscopy Performed for Colorectal Cancer Screening or Surveillance," Gastroenterology , Volume 146 , Issue 3 , 849 – 853 (March 2014).

[vii] See e.g., "Atlantic Health System, UnitedHealthcare launch new ACO partnership," NJBIZ, http://www.njbiz.com/article/20140411/NJBIZ01/140419939/atlantic-health-system-unitedhealthcare-launch-new-aco-partnership; NJ's Horizon BCBS Pays $3M in Shared Savings for Episodes of Care; Readmissions, C-Sections Reduced, American Journal of Managed Care, http://www.ajmc.com/focus-of-the-week/0216/njs-horizon-bcbs-pays-3m-in-shared-savings-for-episodes-of-care-readmissions-c-sections-reduced-.

[viii] 42 C.F.R. § 411.357(l) and (n).

[ix] See e.g., CMS and HHS-OIG Final Waivers in Connection With the Shared Savings Program, 80 Fed. Reg. 66726 (October 29, 2015).

[x] The full list of waivers for various Medicare Alternative Payment Model programs is available at "Fraud and Abuse Waivers," https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html.