September 18, 2011

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Ave., SW
Washington, D.C. 20201

Dear Secretary Sebelius:

RE: [CMS-9989-P] RIN 0938-AQ67 §156.245: U.S. Department of Health and Human Services' Proposed Rule on Implementation of Insurance Exchanges

As we have noted in prior correspondence with the Department, for direct primary care medical home practices, such as Qliance, there is no provision in the Patient Protection and Affordable Healthcare Act (hereinafter the Act) (Pub. L. No. 111-148) as important as Section 1301(a)(3). This section, which enjoyed and continues to enjoy bipartisan and bicameral support, allows qualified direct primary care medical home practices to be part of the insurance exchanges operated by the states. And, it ensures that in the future, Americans around the country will be able to continue to enjoy the improved access to quality care and reduced cost that are the hallmark of this type of primary care.

I. Importance of the Direct Primary Care Medical Home Model:

We recognize that the model envisioned by the authors of this section of the Act is different from traditional fee-for-service insurance and cannot be automatically slotted into an existing regulatory structure. But, this difference, which enables medical practitioners to focus on quality treatment rather than volume, is the key to the unparalleled potential of the direct primary care medical home model.

It is well recognized that over the last thirty years, there has been a steady deterioration in level of primary care provided in this country, just as there has been a seemingly unstoppable rate of inflation in health care costs. At the same time, patients have been increasingly aggravated with the treatment they receive from their doctors, who in turn have been equally frustrated with the pressures they face to juggle an ever growing number of clients just to keep pace with the demands of insurance-based fee-for-service medicine.

These trends are not mutually exclusive. Primary care is the foundation of all health care and the strength of primary care will determine the viability of the rest of the health care system. Direct primary care medical homes, such as Qliance, put an end to this destructive treadmill. They eliminate the counterintuitive incentives which have brought health care in this country to its knees and instead put quality and patient satisfaction, not volume, first.

At Qliance, all services we provide are included in our flat monthly fee. While a few expensive supplies are charged at cost, there is no fee-for-service billing to our patients or their insurers. This low overhead model enables us to put all our resources into the care itself rather than reimbursement overhead. Our providers can spend a minimum of 30 minutes with a patient in each office visit. We limit our patient panels to 800 per provider (compared to an average of 2,500 in the fee-for-service world). We are open 7 days per week and 12 hours per day on weekdays, giving patients same or next day appointments for any urgent issue, plus 24x7 after-hours phone access to a physician on call. And, our patients have a personal physician who knows them as an individual. We are also deploying an electronic medical record that optimizes clinical care, not billing reimbursement.

In sum, we have removed all of the health care misdirection produced by fee-for-service medicine, along with the built-in 40% transaction costs that plague primary care under that system, a system that drives physicians to see 25 to 35 patients a day to cover reimbursement overhead. Our physicians typically see 10-12 patients a day plus provide a handful of phone and email consultations. They have the time to fully treat their patients instead of rushing from one abbreviated appointment to the next. This is especially valuable for patients with one or more chronic diseases.

We also coordinate all care beyond the scope of the primary care we provide directly, an increasingly important service in achieving better medical outcomes at affordable cost in our currently fragmented health care system. We track not only the quality of our work, but also the quality of patient experience in our clinics.

The result of this effort has been a simple, effective, efficient and humane kind of primary care delivery system, a rarity in America today. Our patients use primary care voraciously. We estimate we provide at least 4-8 times more primary care per patient each year than with typical insurance fee-for-service providers. That translates into a dramatic drop in the need for emergency room, hospital and specialist care as well as procedures, surgeries, advanced imaging and the attendant costs and risks these entail. It also translates into happier patients and

providers, and holds the promise to give graduating medical students a reason to aspire to being primary care physicians again.

Our patient satisfaction levels put us in the top 1% of all businesses in the United States for customer satisfaction and far ahead of the general health care sector. Our patients enjoy transparency not only for their costs in our system, but for many of those outside our system. We are putting patients in the driver's seat and empowering them to make decisions that work for them. We perceive our role to be a trusted advisor, not their gatekeeper. As patients accept more financial responsibility for their care, they are interested in spending their money wisely and getting optimal health, not just the most expensive care their insurer will allow.

We believe that by putting Direct Primary Care Medical Homes on the front end of the delivery system, health care will be more effective and patient-centered while driving down costs and unnecessary utilization. And our early data strongly supports that conclusion. Under the Qliance model, there are twice as many primary care office visits (with each visit being 2-4 times longer than under insurance fee-for-service), plus phone and email consultations. As a result, the utilization of emergency room, hospital, specialty care, advanced radiology and surgical care among our under-65 patients is greatly diminished, as seen below in Table 1. This decrease in utilization translates to a net savings of approximately 22% in overall health care costs.

Table 1: Utilization Data – Qliance Members Under 65 (2010)

Type of Referral	Qliance # per year/1000**	Benchmark*	Difference
ER Visits	56	158	-65%
Hospitalizations (visits)	34	53	-35%
Hospitalizations (in days)	105	184	-43%
Specialist Visits	670	2000	-66%
Advanced Radiology	300	800	-63%
Surgeries	22	124	-82%
Primary Care Visits	3540	1847	+92%

*Based on regional benchmarks from Ingenix and other sources.
**Based on best available internal data; may not capture all non-primary care claims

Source: Qliance Medical Group non-Medicare patients, 2010 (n=3,088)

These savings cannot continue, however, if the regulatory process is used to push direct primary care medical homes back into an insurance reimbursement model. The direction of the final rule should not be dictated by regulatory convenience. The rule should be drafted in a manner that ensures that direct primary care medical homes satisfy the applicable requirements

of the Act without having to sacrifice the uniqueness that has enabled these practices to serve more than 100,000 patients in 25 different states.

II. Key Principles for Section 1301(a)(3) Acknowledged in the Proposed Rule

We were encouraged that the proposed rule recognizes two key principles. First, *direct primary care medical homes are premised on the payment of a fee by an individual or on behalf of an individual directly to a medical home for primary care services*, including screening, CMS–9989-P 133 assessment, diagnosis, and treatment for the purpose of promotion of health, and detection and management of disease or injury, consistent with the program established by statute in the state of Washington (RCW 48.150).

We have learned through experience that the relationship between the doctor and the patient changes when patient satisfaction is more important than practice volume. Patients are happier because they are able to see their health care provider when they are sick or in need of treatment, not when it is convenient to the practice. Primary care doctors are happier because they have the time and opportunity to practice medicine as it should be practiced, including the ability to focus on preventive care. The clock is no longer the most important component of health care.

Second, the proposed rule recognized that *direct practice medical homes are providers, not insurance companies.* Simply put, we do not bear any insurance risk and should not be regulated as if we did.

III. Answers to Questions Asked in the Proposed Rule

The Department raised two concerns about the regulation of direct primary care medical homes in its proposed rule. First, it noted that the section would require exchanges to "[d]evelop an accreditation and certification process that is inherently different from certifying health plans and that would significantly depart from the role of an Exchange."

Based upon our experience, this would not be a difficult problem to resolve. As others have commented, organizations such as the National Committee for Quality Assurance (NCQA), an accreditation body nationally accepted by insurers and managed care providers, already has a well-established Patient-Centered Medical Home (PCMH) accreditation program. This particular organization already has developed standards and criteria for patient-centered medical homes. With only slight modification, these could easily be applied to the direct primary care

medical home model, eliminating the need for each state exchange to develop its own accreditation process.

Second, the proposed rule also raised concerns about the administrative difficulties which may arise if consumers are required to make two payments for their full medical coverage, one to the direct primary care medical home and another to the entity providing the required corollary wrap-around insurance. The Department wonders if this would unnecessarily complicate the allocation of advance payments of the premium tax credit.

Again, experience has demonstrated that these concerns are not difficult to resolve. In fact, the dual payment is considered by many patients to be important consumer protection. In Washington State, direct primary care medical home practices are expressly kept separate from insurance. Consequently, our patients must make separate payments to their insurer and their DPCMH practice. Despite this requirement, we have experienced no difficulty with dual payments and are unaware of patients who are reluctant to use our practice because of this requirement.

Most of our patients view the dual payment as an important protection for themselves. By enabling the patient to be the primary customer for the medical services he or she is purchasing from the direct primary care medical home, they are in the best position to monitor the service they are receiving. In addition, this dual arrangement ensures that treatment decisions are agreed upon by the physician and patient. Insurance companies, including the QHPs, are not involved in decisions about which primary care services to cover, since they are not at risk for paying for the services.

Nonetheless, we recognize that the Department may feel that it cannot develop or determine the proper procedure that would permit consumers to pay directly for the direct primary care medical home as well as the wrap-around insurance coverage. In this case, it is important that if the payment for the direct primary care medical home is passed through an insurance company, the regulations protect the contractual ability of the former to prevent an insurance company from using the payment process to re-impose its own standards, requirements and costs on the delivery of primary care.

IV. Additional Issues That Should be Addressed in the Final Rule

In addition to the questions raised in the proposed rule, we suggest that there are other issues that should be addressed when the rule for Section 1301(a)(3) is finalized. The following

represents our attempt to address what we believe are the most important components of regulatory structure for direct primary care medical homes.

(A) Definition of a Qualified Direct Primary Care Medical Home: To qualify as a direct primary care medical home under this section, the entity should satisfy the following criteria:

(1) The entity must sponsor, employ or otherwise be affiliated with a group of health care providers who furnish primary care services for a direct fee;

(2) The entity may not otherwise be regulated as a health care service contractor, or disability insurer;

(3) The entity will not be deemed to be ineligible under this subsection if it also sponsors, employs or is otherwise affiliated with health care providers not engaged in a direct primary care medical home practice;

(4) The entity must furnish primary care services through a direct agreement with the individual or the legal guardians of that individual but may also accept payment on behalf of an individual by that individual's employer or by another entity or person on behalf of the individual;

(5) The entity must provide, in exchange for the direct fee, preventive care, wellness care, acute care, chronic disease management, and care coordination with specialists and hospitals; and

(6) Nothing in this paragraph would preclude a direct primary care medical home from offering hospital care coordination to its patients, including bedside coordination and supervision of the care provided in a hospital.

(B) Definition of a Direct Fee: A direct fee means a fee which may be charged on a periodic basis by a direct practice as consideration for being available to provide and providing primary care services specified in a direct agreement. The direct fee may be paid by a third party including but not limited to an employer.

(C) Definition of a Direct Agreement: A direct agreement is a written agreement entered into between a direct practice and an individual direct patient, or the parent or legal guardian of the direct patient, whereby the direct practice charges a direct fee as consideration for being available to provide and for providing primary care services to the individual direct patient. A direct agreement must describe the specific health care services provided by the direct practice in consideration of the direct fee.

(D) Definition of Primary Care: Primary care means routine health care services, including screening, assessment, diagnosis, and treatment for the purpose of promotion of health, and detection and management of disease or injury, including:

(A) care delivered by primary care physicians, nurse practitioners or physician assistants;

(B) whole person care orientation;

(C) coordinated and integrated care including all routine care, such as vaccinations, routine blood tests, women's health services, acute illness care, minor trauma care and ongoing management of chronic illnesses such as diabetes, hypertension, hyperlipidemia, obesity and depression;

(D) routine scientifically validated preventive services for patients, with priority given to those with chronic diseases or conditions identified by the Secretary;

(E) practice-facilitated local access to the continuum of health care services in the most appropriate setting, including coordination of appropriate specialty care and inpatient services not provided by the direct primary care medical home;

(F) care management support during transitions between care settings;

(G) safe and high quality care through the application of evidence-based medicine, appropriate use of health information technology, and continuous quality improvement; and

(H) twenty-four hour, seven day a week telephonic access to the primary health care provider or a covering provider.

Nothing in this section would preclude a qualified direct primary care medical home from offering to its direct patients services permitted under state law in addition to those listed above.

(E) Prohibition on Discrimination: A qualified direct primary care medical home shall not decline to accept any person solely on account of race, sex, religion, national origin, sexual orientation, age or the presence of any pre-existing health condition.

(F) Payment on a Periodic Basis: A qualified direct primary care medical home may charge a direct fee on a periodic basis. The fee must represent the total amount due for all primary care services specified in the direct agreement and may be paid by the direct patient or on his or her behalf by others. Prepayment of fees for periods greater than a single month should be put into a trust account and may not be accessed in advance of

when the payment is due. If the periodic fee is paid in advance, the direct practice must promptly refund all unearned direct fees following receipt of written notice of termination of the direct agreement from the direct patient. The amount of the direct fee considered earned shall be a proration of the periodic fee as of the date the notice of termination is received.

(G) Payment of Fees: Fees for the qualified direct primary care medical home within the exchange will be paid directly by the individual, employer, or other entity to the qualified direct primary care medical home or may flow through a qualified health plan providing wrap-around insurance as a bundled payment only as a simple pass-through without additional fees, incentives, or restrictions on services imposed by the qualified health plan on the direct primary care medical home.

(H) Maintenance of Records: A qualified direct primary care medical home must maintain appropriate accounts and provide data regarding payments made and services received to direct patients upon request.

(I) Restrictions on Fees: Direct fees for comparable services within a direct practice shall not vary from patient to patient based on health status or sex. The direct fee schedule applying to an existing direct patient may not be increased more frequently than annually.

(J) Contact Person for Patient Complaints: A qualified direct primary care medical home must designate a contact person to receive and address any patient complaints.

(K) Additional Authorized Practices: A qualified direct primary care medical home may enter into a participating provider contract with an insurance carrier for purposes other than payment of claims for services provided to direct patients through a direct agreement. Such providers shall be subject to all other provisions of the participating provider contract applicable to participating providers including but not limited to the right to:

(1) make referrals to other participating providers;

(2) admit the insurance carrier's members to participating hospitals and other health care facilities;

(3) prescribe prescription drugs; and

(4) implement other customary provisions of the participating provider contract not dealing with reimbursement of services.

A qualified direct primary care medical home may pay for charges associated with the provision of routine lab and imaging services. In aggregate such payments per year per direct patient are not to exceed fifteen percent of the total annual direct fee charged that direct patient. This limitation may be exceeded in the event of short-term equipment failure if such failure prevents the provision of care that should not be delayed.

A qualified direct primary care medical home may charge an additional fee to direct patients for supplies, medications, and vaccines provided to direct patients that are specifically excluded under the agreement, provided the direct practice notifies the direct patient of the additional charge prior to their administration or delivery.

(L) Acceptance or Discontinuation of Patients: A qualified direct primary care medical home may not decline to accept new direct patients or discontinue care to existing patients solely because of the patient's health status. A qualified direct primary care medical home may decline to accept a patient if the practice has reached its maximum capacity. So long as the qualified direct primary care medical home provides the patient notice and opportunity to obtain care from another physician, the direct practice may discontinue care for direct patients if:

(1) The patient fails to pay the direct fee under the terms required by the direct agreement;

(2) the patient has performed an act that constitutes fraud;

(3) the patient repeatedly fails to show for scheduled appointments and fails to notify the practice within the time period specified in the direct agreement;

(4) the patient repeatedly fails to comply with the recommended treatment plan and poses a risk to themselves or others;

(5) the patient is abusive and presents an emotional or physical danger to the staff or other patients of the direct practice; or

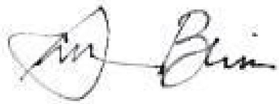
(6) the direct practice discontinues operation as a direct practice.

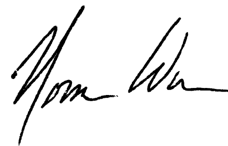
(M) Treatment of Qualified Direct Primary Care Medical Homes: Qualified direct primary care medical homes, as defined in this subsection and that comply with the provisions therein are not insurers, health carriers, health care service contractors, or health maintenance organizations and should not be treated as such, nor shall they be

subject to treatment as insurers or managed care providers under state insurance regulation.

Thank you again for the opportunity to comment on the Proposed Rule on Implementation of Insurance Exchanges. A rule that addresses both the letter and spirit of Section 1301(a)(3) will help the Department address the structural problems with relying exclusively on a fee-for-service model for primary care and give Americans the opportunity to rein in cost while improving the affordability, accessibility, and quality of the care they receive.

Sincerely,





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