Fresenius Medical Care
North America

August 27, 2010

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Affordable Care Act: Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections (OCIIO-9994-IFC)

Dear Secretary Sebelius:

Fresenius Medical Care North America ("FMCNA") is pleased to have this opportunity to submit comments to the Office of Consumer Information and Insurance Oversight ("OCIIO") on the Affordable Care Act: Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections Interim Final Rule ("IFR" or "the Rule"). FMCNA is the largest integrated provider in the country of clinical services and products for persons undergoing treatment for kidney failure, or end stage renal disease ("ESRD"), including chronic renal dialysis. FMCNA operates over 1,800 outpatient dialysis clinics and provides dialysis services to an estimated 136,000 individuals with kidney failure in the United States.

FMCNA commends the Departments of Health and Human Services, Labor, and Treasury (collectively, "the Departments") on their joint efforts to provide guidance to group health plans and health insurance issuers in the group and individual markets on provisions of the Affordable Care Act relating to lifetime and annual limits, preexisting condition exclusions, rescission of coverage, and patient protections. FMCNA strongly supports this set of regulations as they are designed to eliminate some of the most egregious private insurance practices that currently limit access to necessary and appropriate health care services. These new rules will particularly benefit individuals with serious health care conditions, chronic illnesses, and disabilities, including individuals with end stage renal disease.

However, we believe the Rule could be improved in a number of ways to minimize or eliminate limitations on the ability of individuals with ESRD to receive adequate coverage and treatment for their chronic medical condition. Specifically, we urge the Departments to address the following issues:

- Greater protection against condition-based benefit exclusions before the full effective date of the Rule, the year 2014;
- Excessive premiums that may be imposed on children with preexisting condition coverage before the community rating restrictions in the individual market become effective in 2014;
- Restrictions on specific benefit limits (e.g., dollar or treatment frequency) that are imposed to subvert the intent of the annual and lifetime limit protections;
- ESRD care as an "essential health benefit" so the lifetime an annual caps protections will apply to these individuals;
- Continuous private coverage while an individual challenges a rescission and during rescission review periods; and
- Patient access to specialty care through the selection of a nephrologist as a primary care coordinator in private plans that utilize a network of providers.

I. Preexisting Condition Exclusions: Protection Against Condition-Based Benefit Exclusions Before the Effective Date of the Rule

While FMCNA strongly supports the interim final rule prohibiting preexisting condition exclusions, the Rule does not provide necessary patient protections against new condition-based benefit exclusions that may be imposed by health plans and health plan issuers between now and 2014. For instance, to thwart the new rules on preexisting condition exclusions, health plans and health plan issuers could simply eliminate coverage for certain benefits altogether. This could be viewed as a permissible condition-based exclusion of benefits, but would have the same effect as imposing a preexisting condition exclusion. Considering the high medical costs and relatively small number of people with ESRD, there is a significantly higher risk under the Rule that those with ESRD will be subjected to condition-based benefit exclusions between now and the effective date of the Rule (January 1, 2014).

Under the Rule, the preexisting condition exclusion provisions will prohibit not just an exclusion of coverage of <u>specific benefits</u> associated with a preexisting condition in the case of an enrollee, but also a <u>complete exclusion from enrollment</u> in a health plan, if that exclusion is based on a preexisting condition. Considering that the intent of the Rule is to ensure full access to coverage for individuals with preexisting conditions, FMCNA urges the Secretaries to take steps to protect citizens from health plans and health plan issuers that impose new condition-based benefit exclusions in the years prior to implementation of the Rule (when the essential health benefits package has not yet taken effect).

This protection is particularly critical for individuals suffering from chronic conditions, such as kidney failure. ESRD care is precisely the type of condition-based coverage most vulnerable to exclusion given its comparatively high cost. Until 2014, therefore, the Rule should require health plans and health plan issuers to exercise good faith in implementing condition-based exclusions. In this context, "good faith" should be defined to prohibit plans from imposing condition-based benefit exclusions if their effect is to subvert the intent of the new preexisting condition exclusion policy. In this instance, the Department of Labor, Health and Human Services and State Insurance Commissions should have the authority to nullify these condition-based benefit exclusions. In addition, under this "good faith" standard, the Secretaries should mandate continuing coverage for enrollees in health plans who currently have coverage

for their condition (i.e., ESRD care) but may be exposed to a new condition-based benefit exclusion.

II. Prohibition of Excessive Premium Increases for Children Receiving ESRD or other Treatment

FMCNA supports the prohibition of preexisting condition exclusions for dependent children, particularly the provision implementing this rule in September 2010. This coverage protection, however, will not achieve its intended result if excessive premiums may be charged for children with preexisting conditions. Therefore, FMCNA urges the Secretaries to use their regulatory authority to prohibit unreasonable or excessive premium increases for children receiving ESRD or other treatment who receive health coverage through the individual private insurance market.

Currently, federal law prohibits the charging of higher premiums to individuals with preexisting conditions within group plans, but community rating restrictions in the individual market will not become effective until 2014 under the Affordable Care Act. As a result, families with children with preexisting conditions receiving coverage through the individual market may be charged excessive premiums for the next several years. Under the current language of the Rule, children with preexisting conditions may face considerably higher premiums starting in 2010. Depending on how excessive these premium increases become, they could serve as de facto preexisting condition exclusions.

There are several mechanisms that the Secretaries could impose to protect children receiving ESRD and other treatments from excessive premiums in the individual market. For instance, the Secretaries should prohibit health plans from asking questions about a child's health status on insurance applications, minimizing the risk of discriminatory treatment of children receiving ESRD and other forms of costly care. Furthermore, insurance commissioners should be required to monitor premiums for individual family policies with children receiving ESRD treatment and other forms of costly care to ensure that excessive premiums are not being imposed.

Special monitoring will be needed for this patient group to ensure that ESRD status will not essentially become a "preexisting condition" via the high premiums faced by enrollees. A prohibition on unreasonable and excessive premium increases until 2014 is consistent with the Affordable Care Act's intention to provide expanded coverage to children with preexisting conditions.

III. Lifetime and Annual Limits

a. Benefit-Specific Restrictions: With respect to annual limits on essential health benefits, the Rule does not specify whether a plan could apply *benefit-specific limitations*. The Affordable Care Act places restrictions only on "dollar" limits, and does not address non-monetary limits. The Rule also does not indicate whether health plans may limit the number of days or visits for a specific essential or nonessential health benefit.

Different types of illnesses or injuries may require different levels of medical intervention, treatment or care. The acute versus chronic nature of a condition, the complexity of required treatment and other factors may affect the level of care required, and thus, the overall costs

associated with treatment. The chronic and complex nature of ESRD results in high medical costs. When a patient's medical condition advances through the stages of chronic kidney disease ("CKD") and kidney function fails entirely, the patient reaches Stage V CKD, otherwise referred to as end stage renal disease. Patients with ESRD will typically die within several weeks unless they receive regular dialysis treatments to remove fluid and toxins from the bloodstream, or are transplanted with a new kidney. Hemodialysis is typically performed three times each week for three to four hours. Some patients choose to be treated by peritoneal dialysis, where fluid is infused into the peritoneal cavity several times per day in order to remove fluid and toxins.

The treatment of ESRD is multifaceted and costly. It is important that group health plans and health insurance issuers offering group or individual health insurance coverage not be permitted to sidestep the prohibition on lifetime or annual limits by either imposing caps on costs related to the treatment of ESRD or by limiting the number of days of dialysis or number or treatments or procedures that are permitted to treat ESRD. The Secretaries should require that health plans and health insurance issuers act in good faith and impose no restriction or limitation designed to subvert the intent of the annual and lifetime limit restrictions. Such a finding by the Secretary or State Insurance Commissioner should render these types of limitations null and void.

b. Regulatory Moratorium: FMCNA believes that health plans and health insurance issuers may react to the elimination of lifetime limits by imposing new annual limits in benefits subject to the new dollar caps that are permissible until 2014 under the Rule. FMCNA believes that the Departments should promulgate a regulatory moratorium which would prohibit health plans from imposing new annual limits on essential health benefits. That is, no health plan should be permitted to impose an annual limit where none existed prior to enactment of the Affordable Care Act. Such a moratorium would supplement interim final regulations regarding "grandfathered health plans," which state that a health plan or health insurance issuer will lose grandfather status if it imposes annual limits on essential health benefits under any of the following situations:

(a) the plan, on March 23, 2010, did not impose an overall annual or lifetime limit, and subsequently imposes an overall annual limit;
(b) the plan, on March 23, 2010, imposed an overall lifetime limit, and subsequently imposes an annual limit at a dollar value that is lower than the dollar value of the lifetime limit; or
(c) the plan, on March 23, 2010, imposed an overall annual limit and subsequently decreases the annual limit.[1]

c. Application to Large Group and Self-Insured Markets: FMCNA believes that the Secretaries should clarify how restrictions on lifetime and annual limits will apply to large group and self-insured plans, given that such plans will not be required to provide an essential health benefits package. While all plans will use a "good faith" standard for purposes of counting benefit expenditures that qualify under the annual and lifetime caps between now and 2014 (when the essential benefits package is in effect), large group and self-insured plans will use the good faith standard indefinitely. However the good faith standard is defined, it should include health care benefits (such as ESRD care) that mean the difference between life and death.

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[1] 26 CFR 54.9815–1251T(g)(vi), 29 CFR 2590.715–1251(g)(vi), and 45 CFR 147.140(g)(vi).

FMCNA urges the Departments to clarify the good faith standard for this purpose, perhaps by illustrating examples, to make the restrictions on annual and lifetime caps meaningful.

d. Condition-Based Exclusions of Benefits Under Lifetime and Annual Caps: The imposition of restrictions on the use of annual and lifetime caps may have the unintended consequence of prompting health plans and health insurance issuers to impose condition-based exclusions of benefits in order to limit health expenditures in the future. The interim final rule explicitly permits "condition-based exclusions" of benefits. The rule states:

> "The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from excluding all benefits for a condition." Section 147.126(b)(2).

FMCNA strongly urges the Secretaries to clarify in the lifetime and annual caps regulations that condition-based exclusions of benefits must not violate the requirements of the Americans with Disabilities Act of 1990 which prohibits "disability-based distinctions" in health insurance coverage. In fact, in issuing interim guidance on this issue in 1993, the Equal Opportunity Employment Commission (EEOC) stated the following:

> "...health-related insurance distinctions that are based on disability may violate the ADA. A term or provision is "disability-based" if it singles out a particular disability (e.g., deafness, AIDS, schizophrenia), a discrete group of disabilities (e.g., cancer, muscular dystrophies, ***kidney diseases***), or disability in general (e.g., noncoverage of all conditions that substantially limit a major life activity)." See, EEOC Interim Guidance on Application of ADA to Health Insurance, EEOC Compliance Manual, June 8, 1993 (emphasis added).

IV. Essential Health Benefits

As already discussed above, restrictions on lifetime and annual limits only apply to "essential health benefits," a term that is defined in the statute to include ten general benefit categories. Accordingly, regulations that further define the term "essential health benefits" should be issued as soon as practicable.

As a chronic disease and life-threatening condition, *coverage of ESRD should be categorized as an essential health benefit*. The Affordable Care Act requires that the HHS Secretary ensure that the scope of essential health benefits be equal to the scope of benefits provided under a typical employer plan. Virtually all private health plans and public programs currently include coverage of ESRD in their benefit packages. It is important to note that coverage of ESRD includes all aspects of the care of patients with ESRD, including costs associated with transplantation.

Although the Medicare ESRD program provides coverage for eligible individuals with ESRD, Congress did not intend that the entire financial responsibility for coverage of ESRD to be shifted to Medicare. Congress enacted the Medicare as Secondary Payer Act ("MSP") [2] in

[2] 42 U.S.C. § 1395y(b)(2)

1981 in order to "reduce federal spending and to protect the financial well being of the Medicare program." [3] The MSP statute transforms Medicare from being the "primary" payer to being the "secondary" payer in certain situations.

As noted by one federal district court, "The intent of Congress in shifting the burden of primary coverage from Medicare to private insurance carriers was to place the burden where it could best be absorbed." [4] As noted by the Centers for Medicare and Medicaid Services, "In enacting the MSP provisions, Congress intended that the MSP provisions be construed to make Medicare a secondary payer to the maximum extent possible."[5] With respect to coverage of ESRD by group health plans ("GHP") and large group health plans ("LGHP"), the MSP statute limits primary coverage to 30 months after Medicare entitlement, following which Medicare becomes the primary payer and the GHP or LGHP is the secondary payer.

Failure to include coverage of ESRD as an essential health benefit may lead health plans to shift the financial responsibility for the medical care of this chronic patient population to the Medicare program. The inclusion of ESRD as a covered benefit is also consistent with the requirement under the Affordable Care Act that "essential health benefits" include chronic disease management. Additionally, including the coverage of ESRD as an essential health benefit would likely motivate group health plans and health insurance issuers offering group or individual health insurance coverage to seek to improve health outcomes by providing CKD management, prevention and education services.

V. Continuous Private Coverage During Rescission Review Periods

FMCNA supports the prohibitions against arbitrary rescissions of health insurance policies, as plans will only be able to rescind coverage of enrollees in the future based on fraud or intentional misrepresentation. This provision aims to ensure reliable and continuous coverage for individuals, including individuals with ESRD and other chronic illnesses. Accordingly, FMCNA believes an individual should remain covered by a private insurance plan during the review period to determine whether the rescission was appropriate or not. Given the life and death nature of ESRD care, it is imperative that an individual maintain private coverage while a rescission is being challenged or reviewed.

VI. Access to Specialists as Primary Care Coordinators for ESRD Patients

FMCNA urges the Secretaries to strengthen consumer protections developed in the interim final regulations by granting individuals with disabilities and chronic conditions, such as ESRD, greater access to specialists as primary care coordinators. In health plans that utilize a network of providers and require a strong primary care link to the enrollee, the interim final rule permits patients to choose their primary care provider. For some populations, the Rule permits a specialist such as a pediatrician or a gynecologist to serve as the primary care provider. Through their regulatory authority, the Secretaries should permit enrollees with disabilities and chronic conditions, including those with ESRD, who are seen frequently by their specialist practitioner due to the nature of their disease and its treatment, to select a willing specialist to serve as a case

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[3] *U. S. v. Travelers Ins. Co.*, 815 F. Supp. 521, 522 (D. Conn. 1992)
[4] *Provident Life & Accident Co. v. U. S.*, 740 F. Supp. 492 (E.D. Tenn. 1990);
[5] 71 Fed Reg.37 (Feb 24, 2006)

manager or primary care coordinator when the specialist is capable of providing and coordinating primary care services.

Individuals with ESRD interact with their kidney dialysis facility at least three times per week in order to receive necessary care, and they are seen at the facility by their kidney specialist – nephrologist – to direct their kidney care. Given this frequency of contact, the nephrologist often acts as a primary care coordinator. These dialysis facilities and nephrologists function as the default "medical home" for those on dialysis and they are in the best position to act as primary care coordinators. Indeed, in the case of those with ESRD, the nephrologist is often the most appropriate medical professional to serve as the primary care coordinator, since the failure of an entire organ system significantly impacts all other bodily systems.

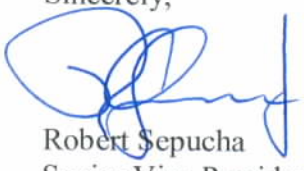
The Institute of Medicine's Committee on the Future of Primary Care has embraced a multidimensional definition of primary care, and we recommend HHS adopt its definition:

> "Primary care is the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community."[6]

This IOM conception of primary care is critical to reducing costs and improving care in the chronic illness and disability patient population in future years. It closely aligns with the concept of the nephrologist as the primary care coordinator of ESRD care. In fact, viewing primary care through its traditional lens will fail to capitalize on the promise of disease management in future years as we, as a country, move to more integrated models of care. FMCNA therefore recommends that the Secretaries define the term "primary care provider" so that specialists can also serve, in appropriate circumstances, as primary care coordinators for people with disabilities and chronic conditions such as ESRD.

Thank you for the opportunity to share our views on this important interim final rule.

Sincerely,



Robert Sepucha
Senior Vice President

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[6] Institute of Medicine, Committee on the Future of Primary Care, *Primary Care: America's Health in a New Era* (Washington: National Academy Press, 1996), p. 31.