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Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-1850
Attention: File Code OCIIO-9994-IFC

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
U.S. Department of Labor
200 Constitution Avenue, N.W.
Washington D.C. 20210
Attention: RIN 1210-AB43

Internal Revenue Service
Room 5205
P.O. Box 7604
Ben Franklin Station
Washington D.C. 20044
Attention: REG-120399-10

Re: Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections Interim Final Rules

Submitted via eRulemaking Portal: www.regulations.gov

Dear Sir or Madam:

I am writing on behalf of America's Health Insurance Plans (AHIP) to offer comments in response to the interim final rule (IFR) concerning Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections published in the *Federal Register* on June 28, 2010 (75 Fed. Reg. 37188). This IFR implements Sections 2704, 2711, 2712, and 2719A of the Public Health Service Act, as amended by the Patient Protection and Affordable Care Act (the "Affordable Care Act"), which was signed into law March 23, 2010.[1]

AHIP is the national association representing approximately 1,300 health insurance plans that provide coverage to more than 200 million Americans. Our members offer a broad range of

[1] Pub. L. No. 111-148, as amended by Pub. L. No. 111-152.

health insurance products in the commercial marketplace and have demonstrated a strong commitment to participation in public programs.

AHIP's members are committed to implementation of the Affordable Care Act and support efforts to expand coverage to the uninsured, particularly for children under age 19, by guaranteeing access to coverage in the individual market without application of a preexisting condition exclusion. We also recognize the important health benefit improvements under the Affordable Care Act, and members of our community support access to primary care providers, pediatricians acting as primary care providers, obstetric and gynecological care, and emergency services, as provided under the Act.

AHIP's comments below are intended to contribute to the successful implementation of the Affordable Care Act provisions addressed in the IFR, while, at the same time, minimize disruptions for consumers and other unintended consequences.

I. Preexisting Condition Exclusions

Subsequent to the publication of the IFR, the Department of Health and Human Services issued a questions and answers document[2] (referred to as Q&As) to assist health plans and states in implementing the requirements for issuing coverage to children under 19 in the individual market. As noted in the Q&As, we appreciate the Administration's recognition of the potential for "adverse selection" and the Q&As allowing specific open enrollment periods to address that concern. Open enrollment periods are key to help keep coverage affordable for all children in the individual market.

In addition, there is recognition of the potential for "premium assistance" programs under state Medicaid and Children's Health Insurance Programs (CHIP) to be used "…as a strategy to transfer vulnerable children to private individual market coverage."[3] The Q&As also state: "The Administration will enforce its current policies on premium assistance and consider new ones if evidence emerges that children with pre-existing conditions are being diverted inappropriately from Medicaid or CHIP to private insurance plans that newly offer guaranteed issue to children regardless of their health status."[4] We support this approach that ensures these vulnerable children continue to receive the scope of coverage that best meets their needs and is consistent with benefits provided in the Medicaid and CHIP programs.

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[2] "Questions and Answers on Enrollment of Children Under 19 Under the New Policy That Prohibits Pre-Existing Condition Exclusions," July 27, 2010
[3] Id.
[4] Id.

The Q&As also address state requirements that establish open enrollment periods and provide that such provisions will not be preempted by federal requirements. As states consider the establishment of open enrollment periods, AHIP and its members will work with the National Association of Insurance Commissioners and individual states to ensure an orderly, consumer-oriented process for access to coverage for children under age 19. Under this process we would recommend an initial open enrollment period, followed by annual open enrollment periods.

II. Lifetime and Annual Limits

A. *Clarify That Coverage Meets the Annual Limit Requirement If the Total of All Essential Health Benefits Paid Equals or Exceeds the Limit*

The IFR prohibits a health insurance plan from establishing any annual limit on the dollar amount of benefits for any individual, except for the allowed restricted annual limits[5], the "floor amounts", for plan or policy years that begin before January 1, 2014. This approach will increase consumer access to essential health benefits, while also considering the cost implications associated with the added consumer protections, as required under the Affordable Care Act.[6] Today, different types of coverage may apply separate annual internal limits on what may be considered to be essential health benefits services, as a means to help keep coverage affordable or to conform to state laws requiring coverage of specific benefits at defined dollar amounts. We believe the IFR language is subject to interpretation with respect to how these types of annual limits are impacted by the requirements for employer and health plan coverage to meet the floor amounts established under the IFR.

AHIP recommends clarification of the language in the IFR that requires the overall annual dollar amount of essential benefits to equal or exceed the floor amount established under the IFR, and that once the total dollar amount of essential benefits paid reaches an annual limit (as established in the plan or policy) that meets or exceeds the IFR floor amount during a plan or policy year, reimbursement for essential benefits will begin again at the start of the next plan or policy year.

B. *Clarify the Application of the Annual Limit Requirements to Value-Based Programs and Care Management Initiatives*

[5] The IFR establishes permissible annual limit restrictions of $750,000 for the first plan year on or after September 23, 2010, $1,250,000 for the next plan year, and $2,000,000 for the next plan year until January 1, 2014. 75 Fed. Reg. 37236 (June 28, 2010).
[6] 75 Fed. Reg. 37191 (June 28, 2010).

We believe that the IFR annual limit requirements should be interpreted in a manner that supports the continued use of consumer incentives to access essential health benefits in a way that promotes value and quality, without unintentionally undermining these tools and techniques. For prescription drugs, there are two examples of programs that use consumer incentives. The first encourages use of mail order pharmacy coverage by requiring lower cost-sharing for mail order drugs and using annual dollar maximums on retail pharmacy coverage. A recent study determined that patients with diabetes who received prescriptions through the mail were 7.8 percentage points more likely to have good medication adherence compared to patients filling prescriptions through a local pharmacy.[7] Such programs provide benefits to patients by encouraging greater adherence to a prescribed treatment and requiring lower cost-sharing levels, and we urge clarification that this type of program complies with the IFR requirements, so long as the mail order coverage meets or exceed the IFR annual floor amounts.

An additional tool for addressing value, while safeguarding quality, occurs in programs that provide incentives for appropriate use of generic drugs. Value and quality have been studied for use of generic drugs, and, as an example, a meta-analysis of generic and brand-name drugs in cardiovascular disease and treatment outcomes demonstrated that the Food and Drug Administration's bioequivalence standard for generic drugs is a reliable "proxy for clinical equivalence among a number of important cardiovascular drugs."[8] To avoid invalidating these types of programs, we urge clarification that annual maximums on brand name drugs are permissible when: 1) generic coverage is either unlimited or subject to the overall annual limit; and 2) coverage of a brand name drug is available on the same basis as the generic, in cases where use of the generic drug is not medically appropriate for the patient.

Both of the above approaches encourage the use of the most cost-effective delivery mechanism and therapy regimen for prescription drugs, without compromising health care quality or access to essential prescription drug benefits.

AHIP recommends clarification that the IFR provisions do not prohibit widely-used programs and initiatives for prescription drug coverage that promote both quality and value, without limiting consumer access to essential health benefits at the required annual amount.

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[7] Duru, O. Kenrik, MD, MSHS, et al. "Mail-Order Pharmacy Use and Adherence to Diabetes-Related Medications." *The American Journal of Managed Care*. Vol. 16, No. 1. 2010: pgs. 33-40.

[8] Kesselheim, Aaron S., MD, JD, MPH, et al. "Clinical Equivalence of Generic and Brand-Name Drugs Used in Cardiovascular Disease." Journal of the American Medical Association. Vol. 300. No. 21. Dec. 3, 2008: pgs. 2514-2526.

C. Clarify That the Scope of the Waiver Program for the Restricted Annual Limit Provisions Applies to a Wide Range of Consumers

The IFR grants to the Secretary of Health and Human Services waiver authority to allow a group health plan or health insurance coverage to be exempt from the restricted annual limit requirements for plan or policy years beginning before January 1, 2014, should the IFR result in a "significant decrease in access to benefits under the plan or health insurance coverage or would significantly increase premiums for the plan or health insurance coverage."[9] In discussion of the waiver program, the preamble states that certain coverage, including limited benefit plans or "mini-med" plans, could be exempt from the restricted annual limit requirements in order to preserve consumer access to medical services and to shield consumers from significant increases in premiums.

We believe the waiver program is an important means to preserve affordable coverage options for consumers prior to the implementation of the 2014 market reforms. In fact, the Affordable Care Act provides for an examination of coverage options that would be impacted by the annual limits requirements to "…ensure that access to needed services is made available with a minimal impact on premiums."[10]

We believe the scope of the waiver should encompass consumers enrolled in a variety of types of comprehensive, major medical coverage. This could include coverage such as, but not limited to, basic medical-surgical expense and basic hospital/medical-surgical expense coverage that are not otherwise classified as HIPAA excepted benefits[11], as well as state-mandated conversion policies that have annual limits that are below the required minimum values under the IFR. These types of coverage should be eligible to be included in the exemption if the group health plan sponsor or group health insurer can demonstrate that meeting the regulatory threshold for the annual limit requirements would result in a significant decrease in access to benefits or a significant increase in premiums.

As the Departments develop further guidance on the scope and procedures for applying for a waiver, AHIP recommends a flexible process that preserves consumer access to affordable coverage options. Allowing reasonable exemptions to the restricted annual limit requirements will reduce disruptions of coverage for consumers and smooth the transition during the 2010 to 2014 transition period.

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[9] 75 Fed. Reg. 37236 (June 28, 2010).
[10] 42 U.S.C. § 300gg-11.
[11] The intent to not apply the Affordable Care Act's market reform provisions to excepted benefits has been previously acknowledged for the new Internet portal and in the preamble of the Interim Final Rules for Grandfathered Health Plans.

D. Clarify the Annual Limit for Essential Benefits with Respect to In-Network Benefits

One of a group health plan's or insurer's primary mechanisms for assuring quality care is to provide incentives to enrollees to receive medical services from accredited, in-network providers. These incentives take the form of lower co-payments and coinsurance amounts, along with a prohibition on balance billing, associated with the use of in-network providers. The incentives to use doctors and hospitals within a health plan's provider network help to lower medical costs for all enrollees and, as a result, help keep coverage affordable. Establishing different annual limits for out-of-network providers reinforces these results, without limiting the overall benefits available to enrollees. Consumers would continue to have coverage for essential benefits that meet the IFR requirements, since the in-network coverage would meet or exceed that requirement. This approach meets the IFR goal of assuring that consumers have a minimum level of essential benefits coverage, while preserving access to quality service from in-network providers.

AHIP recommends a clarification that a health plan meets the IFR requirements if consumers have access to coverage for essential benefits on an annual basis from in-network health care providers that meets or exceeds the IFR requirements.

E. Create a Safe Harbor for Employers and Health Plans for Notifying Retirees of Re-enrollment Opportunity Because of Lifetime Limit Requirements

The IFR requires reenrollment opportunities for individuals whose coverage has ended by reason of reaching a lifetime limit. Health insurance plans and employers are tasked with giving such individuals written notice of their eligibility to reenroll not later than the first day of the first plan year beginning on or after September 23, 2010.

In situations where a group plan covers both active and retired employees, an employer or health plan may have difficulty locating retirees who meet these qualifications and providing timely notice. We suggest the Departments establish a safe harbor for good faith efforts to locate these retirees, under which employers and health plans will not be liable for failure to provide the required notice of reenrollment.

AHIP suggests the establishment of a safe harbor for employers and health plans that make a reasonable, good faith effort to locate retirees who have reached a lifetime limit and may be eligible for reenrollment in coverage.

F. Clarify the Application of Lifetime and Annual Limit Requirements to the Dollar Amount of Essential Benefits Provided

The IFR states that the prohibition on lifetime and annual limits applies to the "dollar amount of benefits," "dollar limits," and "dollar value of all benefits."[12] A plain reading suggests that it would only apply to limits on essential benefits that are expressed in dollars and not to other types of limits such as the number of visits to a category of providers or on the number of days of coverage (e.g., a 20 visit limitation for rehabilitation services). These other types of limits are common in both group health plans and group and individual insurance coverage, and serve to hold down the cost of coverage, while preserving access to services. In some circumstance, without these limits, some employers or other coverage providers may decide to eliminate coverage for these services, as is permissible under the IFR.

AHIP recommends clarification that employers and health plans may continue to establish "day" and "visit" requirements to encourage retention of and consumer access to coverage for these services.

III. Rescissions

A. Clarify the Distinction Between a Cancellation and Rescission

The IFR provides:

> For purposes of these interim final regulations a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, a cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. *As another example, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. (emphasis added)* A cancellation or discontinuance of coverage with only a prospective effect is not a rescission, and neither is a cancellation or discontinuance of coverage that is effective retroactively to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage.[13]

Because the IFR appears to interpret a rescission to include any retroactive cancellation, the IFR seemingly prohibits retroactive administrative corrections of an individual employee's termination of coverage. Example 2 in Section § 54.9815–

[12] 75 Fed. Reg. 3723 (June 28, 2010).
[13] 75 Fed. Reg. 37192 (June 28, 2010).

2712T of the IFR contemplates a mistake in eligibility relating to a change from full-time to part-time status. By extension, this would appear to also apply with respect to other changes in eligibility status, such as termination of employment or other actions that affect eligibility for coverage under a group plan. Such enrollment data is often supplied − by common premium billing practices, in accordance with collectively bargained agreements, or otherwise − on a retroactive basis.

For example, under the Federal Employee Health Benefits Program, under some circumstances, coverage is retroactively terminated effective as of the date of termination of employment, even though the information is not received by a participating health plan, not due to an error, but rather a reporting time lag, until after the date of termination of employment. In other cases, where there is a clerical error regarding an employee's coverage under a plan, coverage may be retroactively terminated weeks or months after the error is corrected. In those cases, the premiums erroneously received are refunded or offset from future premiums owed to the plan. Similarly, in state employee coverage programs, such as CalPERS, eligibility and enrollment information may not be received by a participating health plan until weeks or months after the event giving rise to the change in eligibility status. Under both of these examples, the IFR would appear to require coverage to be extended, and premiums paid, for periods not intended under the terms and conditions of the programs.

The IFR's definition of rescission as applying a cancellation or discontinuance of coverage that has retroactive effect represents a significant change in practice with regard to current, common premium billing practices and correction of clerical errors in enrollment in or eligibility under group health plans.

Traditionally, rescission is a concept of contract law applicable to a broad spectrum of contracts and is grounded in common law and statutory law in many states. Rescission is a remedy that is available when one party has not disclosed material information at the inception of a contract, so that there is no "meeting of the minds" about the agreement. Without this "meeting of the minds," a proper contact is not formed and, as a result, a rescission typically means that the contract never existed. In contrast, a retroactive cancellation implies that the contract was in existence for some period of time.

With the above concept in mind, AHIP suggests that, with respect to group coverage, a clarification be made acknowledging current practices that allow retroactive, "truing up" with respect to eligibility requirements under group coverage, without considering such practices to be rescissions.

B. Clarify That a Health Plan May Provide Notice of a Rescission If, After Good Faith Efforts, It Cannot Complete an Investigation

The IFR is silent as to how the rescission provision would apply in the event that a health plan is unable to complete its investigation of whether there has been fraud or an intentional misrepresentation of a material fact because of an individual's or group's lack of cooperation. For example, there could be a situation where an individual fails to acknowledge a request for information from the health plan or the individual declines to provide consent for a health care provider to provide relevant information to the health plan.

Where a health plan has made good faith efforts to conduct an investigation, but is unable to do so because of non-responsiveness to requests for information or consent, AHIP suggests a clarification that the health plan may proceed to provide the 30-day notice required for a rescission and, if the non-responsiveness continues during the 30-day period, rescind the coverage.

IV. Patient Protections

Choice of Health Care Professional

Consumers Should be Allowed to Make Informed Choices within Long-Established Requirements for Access to Health Care Providers

We strongly support empowering patients to make informed choices with respect to their health care. The Affordable Care Act and the IFR provides three requirements relating to the choice of a health care professional with respect to a plan or health insurance coverage. These requirements support consumer access, without referral, to participating primary care providers, pediatricians (when acting as primary care providers for children), and to obstetrical and gynecological care.

In supporting these provisions, we believe clarification should be made that long-standing requirements with respect to availability of providers are not preempted in allowing access to participating providers. These long-standing requirements with respect to availability recognize that enrollees should not be required to travel long distances to access primary care providers. Indeed, these consumer protections are reflected in many states' existing managed care access laws and regulations[14], as well as in the standards

[14] For example, California has both general and very specific requirements for geographic availability of and accessibility to providers. *See* California Health & Safety Code Sections 1367(e) and 1373.3 and California Code of Regulations, Title 28, Sections 1300.51(d)(H)(i), 1300.67.1 and 1300.67.2.

used for accrediting managed care organizations.[15]

In meeting these requirements and standards, health plans permit enrollees to select from among participating primary care providers in the same geographic area where the enrollee lives or works. In addition to allowing the health plan to comply with these state availability requirements and accreditation standards, this approach helps ensure timely and appropriate care. Studies have shown that consumers more appropriately access needed services, including preventive services, if they live in the same geographic area as their primary care provider.[16]

Additionally, agreements between health plans and physicians or medical groups often address the circumstances under which the physician agrees to accept and treat patients. Under these provisions, a physician's or medical group's obligation will be set forth and include specific geographic areas. Such provisions have the effect of promoting the quality of care, as well as reinforcing the expectation of the provider to treat a certain volume of patients in exchange for the negotiated reimbursement under the agreement with the health plan.

AHIP members support the IFR provisions allowing consumer access, without referral, to participating primary care providers, including pediatricians, and obstetrical and gynecological care and recommend clarification that these provisions do not preempt application of geographic requirements with respect to selection of participating providers.

Coverage of Emergency Services

AHIP and its members strongly support protecting consumer access to emergency services by ensuring that patients do not face barriers before accessing such services or unexpected costs after accessing them. We support the following provisions as consistent with these principles in providing coverage for emergency services:

- No need for consumers to obtain prior authorization (even if the emergency services are provided out-of-network);

[15] *Standards and Guidelines for the Accreditation of Health Plans*, National Committee for Quality Assurance, 2010.

[16] *See, e.g.*, Blewett, Lynn A., PhD, et al. "When a Usual Source of Care and Usual Provider Matter: Adult Prevention and Screening Services." *J Gen Intern Med.* 2008 Sept.; 23(9): pgs. 1354–60; Doescher, Mark P., MD, et al. "Preventive Care: Does Continuity Count?" *J Gen Intern Med.* 2004 June; 19(6): pgs. 632–37; Cardarelli, Roberto, DO, MPH and Thomas, Jennifer E., BS, "Having a Personal Health Care Provider and Receipt of Colorectal Cancer Testing,"*Ann Fam Med.* 2009 Jan.; 7(1): 5–10; Cardarelli, R. et al. "Having a personal healthcare provider and receipt of adequate cervical and breast cancer screening." *J Am Board Fam Med.* 2010 Jan.-Feb.; 23(1): pgs. 75-81.

- No need for consumers to use in-network providers; and
- No need for consumers to pay out-of-network cost-sharing amounts for emergency services.

A. Protect Consumers, Mitigate Costs, and Recognize the Role of State-Specific Factors by Revising the Methodology and Manner of Determining Reimbursement for Emergency Services

We strongly believe that patients should not be subject to unexpected or unreasonable costs when faced with the necessity of utilizing emergency services. The preamble to the IFR, however, indicates that to avoid "defeat[ing] the purpose of the protections in the statute," the regulations go beyond the language of the statute to require that a "reasonable amount be paid for services by some objective standard."[17] The specific approach taken in the IFR, however, may have the unintended consequence of increasing costs for consumers, instead of the intended purpose of mitigating and protecting consumers from such costs.

The IFR uses a three-pronged methodology to set the "reasonable amount" for out-of-network emergency services as the greater of: (1) the median in-network rate; (2) the out-of-network rate (calculated in the manner generally used by the plan); and (3) the Medicare rate.[18] As a general matter, we suggest whether and how to approach the issue of reimbursement in such situations is a decision best left to the states, who can determine the best approach for consumers, based on their needs and the particular market factors in a given state.

Whether included in the IFR or elsewhere, a statutory or regulatory methodology that establishes such reimbursement levels should be both workable and efficient, and not adversely impact consumers. The first prong of the test set forth in the IFR—the median in-network rate—is likely to both undermine networks (harming patients by denying them the quality and cost benefits of networks) and generate significant administrative costs (harming patients by ultimately leading to higher costs).

The first prong is likely to undermine networks because, under the scheme set forth, some providers will have an incentive to drop out of networks to obtain a reimbursement rate that is, by definition, greater than the rate received by half of the in-network providers.[19] This also will have the unintended and undesirable effect of

[17] 75 Fed. Reg. 37194 (June 28, 2010).
[18] 75 Fed. Reg. 37240 (June 28, 2010).
[19] Indeed, the IFR recognizes this potential impact of the test on rates, noting that "[t]hese interim final regulations may also require some health plans to make higher payments to out of network providers than are made under their current contractual arrangements." 75 Fed. Reg. 37213 (June 28, 2010).

increasing the number of patients subject to balance billing by providers.

The monitoring and calculation of a mean rate over broad provider networks and, in some cases, multiple networks, on an ongoing-basis also will be burdensome and expensive, generating significant administrative costs. These costs will be compounded by the absence of geographic, chronological, and other parameters in the calculation as established in the IFR. Thus, the application of the first prong of the test is likely to force consumers to shoulder additional financial responsibilities, resulting from narrower networks for emergency services and more balance billing by providers.

Any methodology that uses the calculation of the "median" amount paid to in-network emergency services providers, should, at the very least, include the following parameters:

- Allow the calculation to be made on an annual basis;
- Allow for good faith, methodology to estimate the median amount; and
- Allow the estimate to be based on categories, e.g., peer hospitals, types of providers, types of products, and different geographic areas.

AHIP recommends the Departments reconsider leaving the determination of whether and how to regulate reimbursement for out-of-network emergency services with the states. If, however, a methodology for determining a "reasonable amount" is retained in the IFR, we recommend removing the first prong of the test (relating to median in-network rates). Alternatively, we recommend establishing parameters, with flexibility, for determining the median in-network amount to protect consumers from the introduction of unnecessary costs in to the system.

B. Protect Consumers from Balance Billing

The Departments have suggested that the statute does not provide authority to enact balance billing protections for consumers.[20] To fully protect patients from unexpected and unreasonable charges, it should be clarified that the Affordable Care Act and IFR do not preempt state laws that prohibit balance billing, and states should be encouraged to act to protect their residents from this practice.

To do this, we suggest a clarification that state laws prohibiting balance billing for out-of-network services that include emergency services are not intended to be preempted. We believe such state laws would not be preempted under section 2724

[20] 75 Fed. Reg. 37194 (June 28, 2010).

of the Public Health Service Act, which would apply to this provision.[21] Here, the establishment, implementation, or continuation in effect of state standards and requirements that prohibit balance billing in such situations would not prevent the application of a requirement of the statute, but rather would be consistent with the underlying goals of protecting patients from unreasonable and unexpected charges.

In addition, we request clarification that the IFR does not prohibit assignment-of-benefits requirements or provisions in health insurance coverage with respect to out-of-network emergency services providers. These provisions allow direct payments to consumers in situations where services are provided by out-of-network providers.

To achieve additional consumer protections, AHIP suggests clarification that the IFR neither disrupts existing state consumer protection laws addressing balance billing prohibitions nor precludes states from enacting new laws in this area.

Further, we request acknowledgement that the IFR applies to comprehensive, major medical coverage, and not to the benefits classified as "excepted benefits" under subsection 2791(c) of the Public Health Service Act. The inapplicability of the Affordable Care Act's insurance and market reform provisions to excepted benefits has been previously acknowledged for the new Internet portal and in the preamble of the Interim Final Rules for Grandfathered Health Plans, and we ask that the same recognition also be made with respect to this IFR.

AHIP remains committed to our continued collaboration and dialogue and stands ready to provide information and support for the effective implementation of the IFR's provisions regarding preexisitng condition exclusions, lifetime and annual dollar limits, rescissions, and patient protections. We appreciate the opportunity to comment on these important expansions of access to coverage, benefits, and health care providers and services.

Sincerely,

Jeffery L. Gabardi
Senior Vice President, State Affairs

[21] 42 USC § 300gg-23.