

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
P.O. Box 8016
Baltimore, Maryland 21244-1850
Attention: OCIO-9994-IFC, RIN 0991-AB69

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration, Room N-5653
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210
Attention: RIN1210-AB43

Internal Revenue Service
CC: PA: LPD: PR, Room 5025
P.O. Box 7604 Ben Franklin Station
Washington, DC 20044
Attention: REG-120399-10

RE: File Code OCIO-9994-IFC, RIN 0991-AB69/ RIN 1210-AB43/REG-120399-10. Requirements for Group Health Plans and Insurance Issuers under the Patient Protection and Affordable Care Act Relating to Pre-Existing Condition Exclusions, Lifetime and Annual Limits, Rescission, and Patient Protections, Final Rule and Proposed Rule

Dear Sirs and Madams,

On behalf of the American Congress of Obstetricians and Gynecologists (ACOG), representing over 54,000 physicians and partners in women's health, I am pleased to offer comments on the Interim Final Rule (IFR) of the Patient Protection and Affordable Care Act (ACA) on Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections ("Patient Bill of Rights").

DIRECT ACCESS TO OB-GYNS

We applaud this new national insurance standard. ACA will guarantee direct access protection to women who reside in states without a direct access law and to women everywhere who are insured under ERISA-protected plans. We have over a decade of experience in 43 states with direct access initiatives, having crafted legislative and regulatory language, as well as practical experience in guiding implementation and monitoring health insurer compliance. We urge you to adopt our specific recommendations in the final rule to ensure women have meaningful access and to avoid the kinds of insurer compliance problems we encountered in the states.

APPLICABILITY

ACOG applauds the Administration for applying the ob-gyn direct access standard broadly to group health plans defined as both *insured* and *self-insured* group plans.

REQUESTED CHANGE:

- We seek clarification that this standard also applies to all individual market plans. The statute states that group health plans, or health insurance issuers offering group or **individual health insurance coverage** must comply with this provision, however only the regulations described in the Department of Health and Human Services section (page 37239) apply this provision to health insurance issuers offering individual health

insurance coverage.

- We are troubled that the ob-gyn direct access standard does not apply to grandfathered plans and urge you to reconsider this in the final rule so that all women who had insurance coverage prior to the enactment of PPACA will have this same protection. By comparison, for example, the rules on rescissions and advance notice do apply to all grandfathered health plans. ACOG believes all women should have direct access to their ob-gyn.

PATIENT PROTECTIONS

To ensure that the national ob-gyn direct access insurance standard delivers meaningful access, we urge the following specific amendments (listed below) and provide language for your consideration from state direct access laws and regulations. Without this specificity, health insurers could define ob-gyn direct access on their own terms and very narrowly. This has been a concern in some states. The language we provide here has been tested and implemented in the states to prevent an erosion of the direct access insurance protections.

- no *age restriction*,
- no restriction on *choice of provider*,
- no *additional cost-sharing*,
- *ensure adequate number of participating ob-gyns*
- *no limit on directly accessed visits, also known as self-referrals, to an ob-gyn, and services for which direct access to ob-gyn providers is protected.*

1. *Specify No Age Restriction.*

The final rule should stipulate that the direct access protections extend to women of all ages, including dependents covered by the participant, beneficiary or enrollee.

State Example:

New York's Health Department guidelines on ob-gyn direct access state, "an enrollee shall include patients of **any age** requiring ob/gyn services."

REQUESTED CHANGE:

- On pages 37226 and 37232 amend "in the case of a female participant or beneficiary" to say "in the case of a female participant or beneficiary, or **covered female dependent, of any age**"
- On page 37239 amend "in the case of a female participant, beneficiary, or enrollee" to say "in the case of a female participant, beneficiary, enrollee or covered female dependent, **of any age**"

2. *Allow Choice of Provider.*

ACOG recommends that the final rule explicitly permit woman to choose their ob-gyn who participates in their plan. This should be the woman's decision, not a provider assigned by the health plan.

State Examples:

New York's direct access law states "A female enrollee shall have unrestricted access to primary and preventive obstetric and gynecologic services from a qualified provider of such services **of her choice.**"

Montana's law states "Each health benefit plan must allow a covered person to select **any** participating obstetrician or gynecologist **of the covered person's choice...** must permit self-referral to **any** participating obstetrician or gynecologist..."

Texas' law states "This subsection does not affect the **right of the woman to select the physician** who provides that care."

REQUESTED CHANGE:

- On pages 37226, 37232, and 37239, amend the sentence "...who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology." to "...who seeks coverage for obstetrical or gynecological care provided by a participating health care professional **of her choice** who specializes in obstetrics or gynecology. The plan may not deny a request for direct access solely because the primary care provider is able and qualified to provide the same care."

3. *Prohibit Additional Cost-Sharing.*

The final rule should prohibit additional cost-sharing on women who self-refer to (directly access) their ob-gyn. Any cost-sharing must not be more restrictive than that for other services and providers in the health insurance plan. Women should not be forced to pay more for self-referring to their ob-gyn.

State Examples:

The prohibition on additional cost-sharing is a protection in most state direct access laws, including Colorado, Delaware, Louisiana, Massachusetts, Missouri, Montana, New Mexico, Ohio, Texas, Utah, Washington, West Virginia, and Wisconsin.

REQUESTED CHANGE:

- Add language in relevant sections, stating "No plan or insurer shall impose cost-sharing, such as copayments, coinsurance, surcharges or deductibles, for directly accessed obstetric or gynecologic services that are not required for access to health care practitioners acting as primary care providers or for other types of health care services not delineated in this section."

4. *Ensure Adequate Number of Participating Ob-Gyns.*

In order to ensure that women have meaningful direct access to ob-gyn care, ACOG recommends the final rule should include a requirement on health insurance plans to contract with sufficient numbers of obstetric and gynecologic providers. Without this requirement, a health plan could contract with a single ob-gyn to serve one or all of its networks, and satisfy the direct access standard. This has been a problem in some states.

State Examples:

This provider contracting requirement is included in the ob-gyn direct access laws in several states including Delaware, Kentucky, Missouri, Montana, New Jersey, New Mexico, Texas, and Washington.

Texas' law states "The plan shall include in the classification of persons authorized to provide medical services under the plan a number of properly credentialed obstetricians and gynecologists sufficient to ensure access to the services that fall within the scope of that credential."

REQUESTED CHANGE:

- Add language, in all relevant sections, stating "Plans shall contract with sufficient numbers of obstetric and gynecologic providers to ensure that female enrollees can exercise their right of direct access without unreasonable delay." Or, "A plan may limit the number of obstetric and gynecologic providers only if there is a sufficient number of obstetric and gynecologic providers available to serve a defined population or geographic service area, so that female enrollees will have direct and timely access to obstetric and gynecological services."

5. *No Limit on Self-referral Visits to an Ob-Gyn.*

We request that the final rule specify that health insurance plans may not limit the number of allowable visits to a participating ob-gyn. Without this requirement, a health plan could limit direct access to one visit annually or one well-woman care visit, and satisfy the direct access standard. This is not the result women want. Women should not have to pay twice the fees and make twice the visits for ob-gyn care. This has been a particular problem with gynecologic care and care for an acute gyn condition. To

prevent this, the final rule, in addition to specifying no limits on self-referral, should specify the covered services that women may self-refer for.

State Example:

Ohio's direct access law includes this requirement, "No insurer may limit the number of allowable visits to a participating obstetrician or gynecologist."

REQUESTED CHANGE:

- Add language, in all relevant sections, stating "No insurer may limit the number of allowable visits to a participating obstetrician or gynecologist for medically necessary primary and preventive obstetric and gynecologic services from a qualified provider of such services of her choice."

6. *Services for which Direct Access to Ob-Gyn Providers is Protected*

In addition to concerns about possible insurer restrictions on the number of visits, ACOG is concerned that the interim final rule does not define the circumstances under which a woman may self-refer to her ob-gyn provider. While we understand that benefit coverage varies from plan to plan and that the rule does not mandate certain benefits, the rule should ensure that so long as the benefit is covered by a plan, a woman may elect to directly access her ob-gyn to receive that care, without prior authorization from the insurance plan, or referral from another provider. At minimum, the protected instances for which women may directly access their ob-gyn provider should include: acute gynecological care; abnormal pap smear treatment; follow-up care for problems discovered and treated during the ob-gyn visit; infertility care; family planning services, annual well-woman visits; and any care related to pregnancy. Spelling this out will ensure that insurance plans do not arbitrarily limit a women's direct access right to only e.g. one annual well-woman visit, while barring women from directly accessing follow-up care based on a condition found during such an annual visit.

State Examples:

California's direct access law specifies that utilization protocols imposed by the insurer may not be more restrictive for ob-gyn services than for other services.

New York's law and Department of Health Guidelines state "The HMO shall not limit direct access to the enrollee's chosen qualified provider for primary and preventive ob-gyn services required as a result of such annual examinations or as a result of an acute gynecological condition. If additional treatment is required for ob-gyn conditions during one or both of the two annual examinations, the follow-up visits would not count as primary/preventive visit. Once a diagnosis is made and follow-up treatment for that diagnosis is necessary, direct access to the qualified provider of ob/gyn services is allowed."

REQUESTED CHANGE:

- Add language, in all relevant sections, stating "Direct access to health care services provided by ob-gyn providers **includes, but is not limited to:** annual well-woman examinations; care related to pregnancy; family planning services; care for all active gynecologic conditions; and diagnosis, treatment and referral for any disease or condition within the scope of the professional practice of a properly credentialed ob-gyn provider."

NOTIFICATION REQUIREMENTS

Our experience in the states has shown us that women's knowledge of their right of direct access is critical to successful implementation of this patient protection.

1. *Notice to Patients of Their Right to Direct Access.*

ACOG greatly appreciates the IFR's requirement on the health plan to issue a notice to beneficiaries, enrollees, and participants, informing them of their right to directly access an ob-gyn provider. We believe the below suggested edits will serve to strengthen the proposed language.

REQUESTED CHANGE:

- Amend the rule language with the items in bold:
“You do not need prior authorization from [name of group health plan or issuer] or **a referral** from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology, **regardless of whether or not your primary care provider can provide that care.** The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. **You cannot be charged any additional amounts for choosing to directly access care from an ob-gyn provider, beyond what you would be required to pay for care received by your primary care provider.** For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].”

2. *Reporting Requirements on the Ob-Gyn Provider.*

ACOG understands that in order to promote coordination of care, health insurance issuers and group health plans may require the directly accessed ob-gyn provider to forward information concerning medical care of the patient to the primary care provider or the plan or issuer, after a directly accessed ob-gyn visit. Any such requirement however should include protections for the ob-gyn provider and the patient against financial penalties or reimbursement denials, provided that the ob-gyn provider made a good-faith effort to report such information.

State Examples:

Texas’ ob-gyn direct access law protects both the patient and the ob-gyn from any penalty, provided a good-faith effort was made to forward information to the primary care physician.

New York’s Health Department guidelines on ob-gyn direct access protect both the patient and primary care provider from financial or other penalties being imposed because of failure to report by the ob-gyn provider. Additionally, New York’s guidelines specify “if an enrollee directly accesses her qualified provider of ob/gyn services for what the enrollee perceives as symptoms resembling an acute ob-gyn condition, then the qualified provider of ob/gyn services should document those presenting symptoms so that the direct access visit can be reasonably explained to the HMO and reimbursed, even if the actual diagnosis turns out to be non-gynecologic. Appropriateness of the direct referral is based on symptoms, not the actual diagnosis.”

REQUESTED CHANGE:

- Add language in all relevant sections, stating “Failure to provide this information may not result in any penalty, financial or otherwise, being imposed upon the ob-gyn provider or the patient by the health plan, if the ob-gyn provider has made a reasonable and good-faith effort to provide information to the primary care provider and the health plan or issuer. If a woman directly accesses her qualified provider of ob/gyn services for what she perceives as symptoms resembling an acute ob-gyn condition, the plan may require that the provider document those presenting symptoms so that the direct access visit can be reasonably explained and reimbursed, even if the actual diagnosis turns out to be non-gynecologic. Appropriateness of the direct referral is based on symptoms, not the actual diagnosis.”

ENFORCEMENT

The lack of federal enforcement on insurance market abuses is a major reason why the Patient Bill of Rights regulations are so badly needed. The IFR however does not address enforcement mechanisms for failure to adhere to the new national direct access insurance standard. We urge the final rule to authorize enforcement and oversight, specifying the oversight and enforcement agency, as well as clarifying federal and state responsibilities. The state experience with ob-gyn direct access and other patient protections clearly favors strong oversight and enforcement.

State Examples:

Colorado, Montana, New Mexico, New York, and Washington are among states that have implemented strong oversight and enforcement mechanisms.

Montana's ob-gyn direct access law states:

"If the commissioner determines that a health benefit plan does not comply with (sections 1 through 8) or that a health carrier has not complied with (sections 1 through 8), the commissioner may:

- (1) recommend a correction plan that must be followed by the health carrier;
- (2) institute corrective action that must be followed by the health carrier;
- (3) suspend or revoke the certificate of authority or deny the health carrier's application for a certificate of authority; or
- (4) use any of the commissioner's enforcement powers to obtain the health carrier's compliance with (sections 1 through 8)

REQUESTED CHANGE:

- o ACOG recommends adding language in all relevant sections, similar to the language on page 37208 on enforcement of rescissions, as well as borrowing from the Montana law. Additionally, ACOG recommends the HHS Secretary use her power to not certify a plan for participation in the Health Insurance Exchanges, if it does not comply with direct access laws.

OTHER

- o On page 37225, the regulation cites a "temporary expiration date June 21, 2013" ACOG requests clarification on this provision. Specifically, ACOG wants to ensure that there is not a gap of patient protections between the June 21, 2013 and the commencement of the remaining insurance market reforms on January 1, 2014.

PATIENT DESIGNATION OF PRIMARY CARE PROVIDER

ACOG fully supports this provision and a patient's right to designate a participating primary care provider of their choosing, in cases where the group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation of a participating primary care provider.

REQUESTED CHANGE:

- o We note however that the IFR does not provide a definition of who qualifies as a primary care provider. We urge you to recognize in the final rule that ob-gyns can be eligible primary care providers for women. For many women, especially women of reproductive age 18-44, the ob-gyn is their primary care provider. Currently 17 states require that insurance plans contract with ob-gyns as primary care providers, if the ob-gyn applies for such designation. In three additional states, health plans have the option to contract with ob-gyns as primary care providers. The final rule should apply this nationally to protect a woman's right to elect her ob-gyn as a primary care provider and to allow any qualified ob-gyn to contract with a health plan as a primary care provider.

PRE-EXISTING CONDITION EXCLUSIONS FOR CHILDREN/ADULTS

We are pleased that the interim final rule clearly prohibits the denial of coverage based on health status and the exclusion of coverage of specific benefits associated with a pre-existing condition for children under 19 in plan years beginning on or after September 23, 2010 and for adults in plan years beginning on or after January 1, 2014. In order to strengthen the protections and to fulfill the promise of the ACA, we recommend the following improvements to the interim final rule:

REQUESTED CHANGES:

- *The final rule should include excessive waiting periods in the definition of pre-existing condition exclusions. An excessive waiting period should be defined as any period longer than 90 days, in line with the ACA provision that will go into effect on January 1, 2014. Without such an inclusion, children with pre-existing conditions will continue to face delays in access to necessary coverage and care for their health conditions.*
- *The final rule should explicitly allow the Secretary of Health and Human Services to use her/his regulatory authority under Section 2794 to prohibit unreasonable premium increases and/or excessive premiums for families with children with pre-existing conditions. Without such authority, insurers may charge newly covered children with pre-existing conditions excessively high premiums or significantly increase premiums for currently covered children based on their health status, making coverage unaffordable and unattainable for families. Allowing such high premiums and premium increases goes against the intention of this provision of the ACA, to expand health coverage to more children.*
- *If states allow limited open enrollment periods for children, they should be required to have special enrollment periods in individual market policies as well as group policies. On July 28, the Administration issued new guidance regarding the sale of health plans to children with pre-existing conditions that permits open enrollment periods in the individual market, as allowed under state law. We appreciate this new guidance and request that for states without laws on the timing and duration of open enrollment periods, the final rule should, at a minimum, establish special enrollment period rules for the individual market, paralleling the rules of the group market. Special enrollment periods will provide families the opportunity to learn about and understand their coverage options and make educated decisions. Moreover, during the first year in which coverage is available to children without regard to pre-existing conditions, plans should not restrict enrollment periods or should allow liberal exemptions to any open enrollment periods, since it will take time for many families to learn about their new rights to coverage and seek enrollment.*

RESCISSIONS

The regulation prohibits plans from rescinding coverage “unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by terms of the plan or coverage.” This addresses, and will hopefully end, the practice of insurers retroactively cancelling coverage based on mistakes or unintentional omissions on an enrollee’s application. We appreciate the clarification that more protective federal or state laws may apply without preemption and the admonition in the regulation’s preamble that the Department will be watching for “attempts in the marketplace to subvert these rules.” This watchfulness is necessary given insurers’ continued battle over rescission rules in the states. Additionally we recommend the following enhancements:

REQUESTED CHANGE:

- *Standards Regarding Health Questionnaires*

One way for insurers to collect health information on prospective plan enrollees is through a health questionnaire. Potential enrollees should be informed in writing that information collected on a health questionnaire by an insurer, or an employer on an insurer’s behalf, can potentially be cited as evidence of fraud or intentional misrepresentation at the time of application or at any time during the life of the policy.

In addition, the regulation should set minimum standards for the content of health questionnaires. Without commonsense protections, a confusing, ambiguous, or misleading questionnaire may be set as a trap for consumers and allow insurers to violate the spirit of the rescission restrictions. At a minimum, questionnaires should use clear, unambiguous, lay-person language in discussing a prospective enrollee’s medical history. Questions should only elicit medical information that is reasonable and necessary for medical underwriting, and each question should clearly state the time frame covered. Also, questions should not require an applicant to guess what symptoms are significant to the health insurer or to understand the medical significance of

symptoms or conditions. Applicants should also have the opportunity to indicate where they are unsure of an answer.

o *30-Day Advance Notice of Rescission*

In the past, many consumers have faced rescission without the benefit of any advance notice, so a 30 calendar-day window in which to begin the process of contesting the insurer's decision or to find alternative coverage is a good start. The notice should be delivered by certified mail with return receipt requested, or by similar timely method that provides proof of delivery, to ensure the notice arrives in the hands of the enrollee. The 30-day clock should begin when the enrollee receives the notification, not when it is sent.

The regulation should also make clear what kind of information must be contained in the 30-day notice. At a minimum, the notice should include:

- a detailed explanation of the reason for rescission, including the legal standard for rescission and the ways in which the insurer believes the consumer has committed fraud or intentional misrepresentation of a material fact;
- a statement acknowledging that the insurer, not the beneficiary, bears the burden of proof;
- an affirmation of the beneficiary's right to obtain copies of any and all information used in making this determination and an explanation of how this documentation can be obtained;
- a description of any federal or state consumer protections that exist, such as the right to an appeal;
- a description of how an appeal can be initiated and of the levels of appeal available to the consumer;
- a statement that tells the consumer about his/her right to fight the insurer's decision to rescind in court;
- a clear indication of the date the rescission decision takes effect and the date of the retroactive loss of coverage; and
- an itemized accounting of pending or previously-reimbursed medical expenses that will be recouped by the insurer, with provider's name and contact information.

Again, thank you for the opportunity to comment on the Interim Final Patient Bill of Rights Rule. We hope you have found our comments helpful. Should you have any questions, please contact ACOG's Government Affairs Manager, Nevena Minor at nminor@acog.org or 202-314-2322.

Sincerely,



Richard N. Waldman, MD, FACOG
President