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General Comment

See attached file(s)

Attachments

IRS-2010-0021-0014.1: Comment on FR Doc # 2010-18043

September 21, 2010

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Attention: RIN 1210-AB45; RIN 0091-AB70; RIN 1545-BJ63 *(delivered electronically)*

A. DESCRIPTION OF THE RESPONDENT—MAXIMUS FEDERAL SERVICES, INC. (FORMERLY, CENTER FOR HEALTH DISPUTE RESOLUTION-CHDR)

MAXIMUS Federal Services Inc. (MAXIMUS Federal) is pleased to comment on the Interim Final Rules (the Rules) for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes under the Patient Protection and Affordable Care Act (the ACA). As a provider of appeal services to federal and state regulators, our foremost role is to operate appeal programs in compliance with statute, regulation and contract. We are not a policy research organization. However, our experience in appeal program implementation—and in particular with insured patients' successes and frustrations with appeals—is relevant to rule making in this area.

MAXIMUS Federal, a URAC accredited Independent Review Organization (IRO), has provided external appeals since 1989 and is by far the largest provider of independent external review care appeal programs in the United States. Formerly operating as the Center for Health Dispute Resolution (CHDR), our clients include the Centers for Medicare and Medicaid Services (CMS), the Unites States Office of Personnel Management (OPM), the Department of Defense, the Department of Veterans Affairs and more than 35 state regulatory agencies which follow the NAIC Model Act or a derivation thereof.

Since 1989, we have completed more than 800,000 health care appeals. Most IROs primary experience lies in medical necessity and experimental/investigational appeals, often in states that follow the NAIC model or a derivate. We have the unique additional experience of operating government regulated appeal programs that rely upon a different statutory base, hence which are implemented with different models. For example, in providing appeals for Medicare Part A, B, C and D, we implement the Qualified Independent Contractor Program (QIC) in accord with the Balanced Budget Act and Medicare Modernization Act. The QIC model differs from the NAIC model in that all denials (coverage and medical necessity) are subject to independent external appeal. The appeal models for OPM and DoD represent some features common to both NAIC and Medicare. Within States, we address program requirements which are strictly in accord with NAIC (and would be meeting the currently proposed standards of the Interim Rule) as well as programs that either exceed or fall below NAIC standards. We also have provided (external) appeals directly for forward thinking employers and ERISA plans who voluntarily offer this patient protection. To meet the demands of this mix of models our professionals include health attorneys, coding and reimbursement specialists, and experts in health insurance operations -- in addition to many Board certified physicians customarily associated with IROs.

Our history and expertise across all appeal models informs our views on the experience of consumer appellants, plans and regulators with these unique models. While we recognize that the Secretary must regulate within the statutory appeal provisions of ACA, we believe contributions to the regulation should be offered from the broadest possible perspective. For this reason, we first share our perspective on consumer and other stakeholder expectations vis-à-vis appeals and provide an overview of the current appeal landscape. We take the liberty of offering a set of goals the appeal program — hence the regulation — should be designed to obtain.

B. CONSUMER EXPECTATIONS

As the Department stated in the Interim Rule Background, an effective due-process appeals system is recognized to be a critical patient protection. This general assertion is supported by stakeholders as diverse as consumer groups, AHIP, NAIC, employers and unions. Although there is no controversy about the need for some appeal system, the rationale for this due process protection is worth considering.

Health insurance design/operations and clinical medical care are among the most complex and rule based enterprises — if not the most complex systems — that exist. These systems, rules and operations are inherently imperfect as well as confusing to the most literate consumers. Whatever communication, management, computer system and quality models are deployed will therefore fail in a given instance (that is, "to err is human"). Sometimes, this failure takes the form of a withholding or denial of insurance coverage and/or medical care to which an enrollee/patient is actually entitled, or to which the enrollee strongly believes she is entitled.

When faced with denials, consumers are not appeal happy as demonstrated by low rates of appeals, particularly at the external level[1]. But, this does not mean consumers are indifferent to the availability or design of the appeal program. We find that consumers fairly uniformly expect an independent, comprehensive, straightforward, easy to comprehend and easy to use appeal process. Following from these process expectations, consumers also expect fair and timely decisions that acknowledge their arguments, reflect expert opinion and provide a decision rationale that, while faithful to insurance and clinical technicalities, can be understood by the lay person.

Conversely, consumers express profound frustration if they are forced to go thru multiple appeal "doors" depending on the type or structure of insurance, if some denials are eligible for appeal but some are not, and if the rules and processes for appeal are just as complex as are the underlying insurance operation and medical system. Because consumers are first offered (internal) appeals by their insurance administrator, they are often profoundly skeptical that appeal decision makers are in fact independent. "Who picked you" or "Who pays you" are often the first words spoken by the consumer appellant.

Of course some consumers are satisfied with the appeal experience only if they "win" — notwithstanding the strength of their argument. However, we think it is important to register our experience which is that overwhelmingly consumers are reasonable people when treated reasonably. Specifically, if the appeal system and its product conform with the expectations for fairness, professionalism and ease of use, consumers accept well-reasoned denials as well as approval of their care. This is another way of saying that the ACA statute and the Departments' regulations have profound impact not only in constructing a technically sound due-process system, but also one that satisfies consumers that due process has been delivered.

C. PLANS AND PAYORS

The Departments' Background and Impact assessments correctly note that a strong appeal system not only protects consumers, it is also benefits health insurers, plans and payors (for example, employers). An independent appeal system confirms to patients that a denial is fair and appropriate and in doing so confirms the legitimacy of (necessary) limits in insurance coverage. Plans and payors have also found that quantitative and qualitative appeal information is a powerful source of data for continuous improvement.[2]

It is clear from the debate leading to the ACA that some express concern that decisions may be made to withhold necessary care from patients. This is not unlike the managed care outcry that arose in the 1990s and which birthed "patient protection" discussions in that decade. Then, as now, "appeals" emerged as a remedy to concerns about inappropriate rationing.

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[1] The Regulation cites an external appeal rate of 1.3 per 10,000. While our data demonstrates that the appeal rates can and should be higher (that is, Medicare model), even for this population the external rate does not exceed 3 appeals per 1,000.

[2] We will propose that the Departments enhance the interim rule by adding provisions for sensible appeal data collection and reporting.

It may be useful to the Departments to know that when early stage appeal programs (for example, Medicare Reconsideration) were implemented in the early 1990s the industry initially reacted with skepticism if not alarm. Among the issues noted was the potential that the appeal program would arbitrarily "expand" benefit packages and that it would involve substantial administrative cost or that it would foment malpractice or plan related law suits. However, none of these fears materialized and industry leadership quickly supported appeal provisions in regulation and accreditation standards.

Generally speaking, plans and IROs now enjoy a positive and collaborative relationship. However, historical concerns regarding appeals are again being voiced. In particular, entities not previously subject to certain appeal provisions (for example, ERISA plans with respect to external appeals) have raised the specter of benefit expansion and litigation. Because there is a 20-year history which disproves these fears, we urge the Departments' not to limit or reduce provisions which require a comprehensive and vigorous appeal program.

Finally, we recommend that while the Departments acknowledge the general pattern of industry cooperation with appeals programs, it should recognize that appeal programs are most needed as a remedy for outlier practices. It is those plans that exhibit patterns of inappropriate denials that may fail to comply with basic appeal requirements in the area of notice, timely escalation, and so on. Experience over the past 20 years has shown that consumer utilization of appeals (that is, appeal rates) is a function of plan compliance, and plan compliance is in turn directly responsive to regulator outreach audit and oversight. We urge the Department to determine the need and opportunity to set forth oversight and compliance measures in the regulation, but if not, to otherwise announce a rigorous compliance program addressing both state and federal appeals systems.

D. CURRENT APPEALS ENVIRONMENT

The Department's Economic Impact Statement (p. 41) concludes that "these interim regulations will help transform the current, highly variable health claims and appeals process into a more uniform and structured process." We agree it is necessary to hold the ACA provisions and the resulting regulations to these standards. However, if there is a goal of uniformity, we would urge the Department to acknowledge that the "current, highly variable" systems are not depicted or captured only or primarily in a review of State (NAIC) versus DOL (ERISA) practices. Millions of Americans are covered by Medicare, Medicaid, CHIP, FEHBP, DoD and VA. The appeal provisions in these programs differ substantially from the NAIC Model and, depending upon the ultimate approach to the "federal process" in the Rule, perhaps form the future ERISA appeal program.

The extent to which the Departments' reviewed and considered the specific features of these alternative programs vis-à-vis the regulation is not explicit in the Interim Rule Background. We urge the Department's to do so for two reasons. First, we believe these programs, and in particular the Medicare Qualified Independent Contractor (QIC) model, present best practices. Secondly, consumers will transition to or from these programs into ERISA or state regulated

plans and/or will have family members with different coverage. A parent of a special needs child, who has contended with the Medicaid Fair Hearing process to secure an appropriate off-formulary drug, should ideally not have to later undergo a (different but redundant) ERISA appeals process — which would not offer a determinative "external" review if the plan was "grandfathered." We recognize that the ACA and other health program statutes do not provide the Departments with an immediate ability to require a truly uniform appeal program. However, we encourage the Departments, if they have not done so, to initiate the analysis that could provide the basis for this direction.

We note that commentary in the interim rule indicates that the Departments may have concluded that either Congress intended, or it is otherwise desirable, to have appeal programs conform with the NAIC model where possible. This philosophy may be reflected in the recent DOL interim procedure with offers non-grandfathered ERISA plans a safe-harbor if they contract for (external) appeals via a State program or in a manner comparable to the NAIC model. If the Departments believe the existing state (NAIC) model represents either the best or the most common practice across *all* plans we urge the Department to reconsider. We will offer information and recommendation which demonstrates that the Medicare QIC model is a more comprehensive and more consumer friendly process with a high rate of plan compliance nationwide. In addition, the appeal program requirements for Medicaid, CHIP, TRICARE and VA share many more common elements with the Medicare QIC model than with the NAIC model[3].

E. GOALS FOR ASSESSMENT OF APPEAL POLICY

The current complex array of appeal policies and programs as well as the legislative mandate within the ACA and other health program statute greatly constrain the Department in constructing the Interim Rule. Nevertheless, we recommend that the Department make explicit the goals it is striving to achieve, while faithful to the legislation, so that the merits and deficiencies of the regulation are more apparent. We suggest consideration of the following goals:

1. Comprehensive Scope

Consumers will have a statutory and regulatory right to obtain an unbiased and professional internal and external appeal for **all** claim or prior authorization request denials—in whole or part—and for any reason.

[3] Our preference for the Medicare Model versus NAIC Model is with reference to the rules that govern these appeal programs (for example, definition of denials eligible for appeal, notice requirements, method of IRO contracting, and so on). We are specifically not making a particular federalism argument (that is, whether the responsibility for administration of a more common appeal policy should rest with the States, the federal government, or some combination).

This goal implies that all eligibility requirements with respect to the nature of the dispute are eliminated, hence parties that have vested interests (for example, plans) are not in the position to determine the "eligibility" of the appeal issue.

2. Ease of Consumer Access and Use

Appeal process policies will keep the burden on the consumer to that minimum which is necessary to bring forward — *one time* — the consumer's appeal and basic arguments.

This goal argues against impediments to appeals such as but not limited to: filing fees, unreasonable or impractical procedures for appointment of representative, unclear or complex requirements with respect to how and where to file, requirements to obtain provider justifications/recommendations in order to file, limitations on access to appeal entities and requirements to provide case file information (as opposed to the opportunity to provide information). Appeals which are not found fully "favorable" at a first level should be automatically escalated (by the plan) to the higher level.

3. Prompt, Complete and Understandable Notice

Initial and appeal (prior authorization) decisions should be made in a timeframe that is consistent with the urgency of the patient's medical condition. Retrospective decisions should be made within 30 days. The complete basis for the decision, including easy access to all internal policies or referenced external standards (for example, literature) should be presented in a form that is technically correct but which a lay person can comprehend. Culturally sensitive translation should be provided to non English speakers.

Decisions (notices) at each level should clearly define the availability and means to access appeals at higher levels.

4. Consumer Assistance

Appeal policies should promote, not inhibit, the consumer's engagement of an advocate. Every consumer should be offered the option to consult and engage an independent advocate, such as provided by a regulator Ombudsman office.

Consumers should have easy and free access to the entire appeal case file and an opportunity to add to the record, but should not be required to fulfill plan obligations for record or provider production. At the level of independent IRO appeal, timeliness rules should be flexible to permit the IRO to make sensible tradeoffs in appeal completion date vs. the time permitted for consumer case review and input.

5. IRO Decisionmakers

The current accreditation standards with respect to IRO medical professional credentialing are sound and should be maintained. Conversely, the standards are weak and require substantial refinement with respect to non-physician professionals called upon to make due process, benefit interpretation or reimbursement decisions. These decisions should not be delegated to physician reviewers.

6. Independence/Conflict of Interest re: Insurers and Plans

IRO independence from insurers and benefit plans should be strict and transparent to consumers. Plans should neither select nor directly pay an IRO for an external level of appeal. An IRO that has a financial relationship with a health plan—including contracted provision of internal review or any consulting services—should not be eligible to provide external review. In considering the conflicts of an IRO that is a subsidiary, the relationships and activities of the parent should be evaluated as if they directly attached to the IRO subsidiary.

7. Independence/Conflict re: Regulators

Regulators have a proper role in selecting and monitoring IROs. This can and should include such measures as retrospective evaluation of sample cases. However, regulators should be precluded from entering contemporaneously into decisionmaking of an open case.

8. Effectuation

The IRO or the regulator should have specific authority to routinely obtain confirmation from plans that an overturned service has been provider or bill paid.

9. Compliance Monitoring

Regulators should be funded to regularly audit plan compliance with appeal policy including statistically valid sampling of adverse determinations.

10. Reporting

Reporting should be required on case specific, but confidential basis so that the processing of a case can be tracked from adverse determination to the completion of all levels of appeal.

F. ADDITIONAL COMMENTS ON RULE BACKGROUND AND IMPACT STATEMENT

These sections include estimates of the likely rate and number of appeals. The data sources for these estimates are familiar to us. Although the researchers who provided these estimates are highly regarded, the underlying data is of poor quality. In addition, the data is primarily drawn from the experience of State regulated appeal programs. Although these programs vary in design, they generally follow the NAIC Uniform Model Act in defining only medical necessity and experimental and investigational denials as subject to appeal. Consequently, these data sources do not reflect the experience that would occur if consumers were also entitled to appeal so called "coverage" denials such as encompassed in the DOL "adverse determinations" definition. A final consideration in interpreting the appeal data is that many States lacked sufficient funding at the time to routinely monitor plan compliance with appeal requirements, or to provide consumers with substantial levels of assistance.

With these caveats in mind, the Impact assessment estimates that the external appeal rate would be only 1.3 appeals per 10,000 enrolled participants. We believe this is a dramatic underestimate of the rate of external appeals that would arise in the State process, if appeal eligibility is extended to "coverage" denials and given the additional resources ACA provides States for consumer support. The estimate is, in our opinion, decidedly low for self insured ERISA plans for which the DOL "adverse determination" definition will apply.

Highly reliable data at the reconsideration level (comparable to external IRO appeal) is collected in the Medicare Appeal program in the Medicare Appeal System (MAS). In Medicare, the best analogy to a mix of insurance offerings is found in Part C of Medicare Advantage. Like DOL, Medicare provides appeals for denials of all types of adverse determination (that is, coverage and medical necessity). Approximately 80 percent of Medicare appeals are "coverage" denials, hence only 20 percent of adverse determinations are presented by plans as "medical necessity" denials. In addition, the Medicare managed care appeals process has been in place in largely the same form since 1989 and first HCFA and then CMS placed considerable emphasis on health plan appeal compliance.

We estimate the external appeal rate for Medicare Part C to be currently 3 per 1,000 enrollees. Since we have tracked this measure since the early 1990s, is has never dropped below 1 per 1,000 and has averaged above 2 per 1,000. Although Medicare beneficiaries obviously have greater health care needs than non-seniors, hence exposure to denials, it is unlikely that this difference accounts for an external appeal rate that is 20 times higher than the rate estimated in the Impact Statement.

The higher Medicare external appeal rate has, in our opinion, a number of implications. First, it supports our argument that if external appeals are limited to "medical necessity" consumers will lack a remedy for the majority of denials made by plans. We will below provide examples of "coverage" appeals that demonstrate that these disputes are not frivolous. Second, the Medicare data and experience demonstrates the importance of regulatory compliance efforts. Third, we are

concerned that in relying upon the substantially lower estimates the Departments might, without intent, set very low expectations for appeal system performance. Fourth, while the higher rate of Medicare appeals does raise the cost estimate for the regulation, the Medicare (QIC) competitive contracting process and high volume economies of scale do result in "per appeal" costs that are less than half of the $605 estimate in the impact statement.

G. REGULATION TEXT COMMENTS

Scope

The Departments should request and support a legislative amendment to the Affordable Care Act to remove the exemption of "grandfathered" health plans from the External Appeal provisions.

In multiple sections of the Background the Departments argue that the intent of Congress was to both extend patient protections (appeals) and reduce complications and inconsistencies that currently exist in appeal law and policies that apply to different forms of health plans at the state and federal level. We believe there is widespread support across divergent stakeholders for pursuit of these goals. Consequently, we believe it is unlikely that Congress intended that the ACA appeal provisions would actually add additional complexity and unevenness in patient protection. However, by applying the grandfather exemption to the appeals provisions, Congress in fact furthered inconsistencies in appeal policies. More importantly, Congress legislated the exclusion of millions of Americans from this most vital—but least controversial—patient protection.

The regulatory Impact analysis estimates that over 80 percent of large employer plan and 70 percent of small employer plans would enjoy grandfather status as of the regulation's effective date. This translates to an estimated 105 million Americans who will initially have no right to any form of independent external appeal of a health plan denial. Even with a robust estimate of the rate of conversion of grandfathered plans, the Departments' analysis implies 59 million Americans would be absent this protection in 2013.

We recognize that the likelihood of the amendment we recommend to the Affordable Care Act is uncertain. In the interim, we recommend that the Departments retain focus on Americans without external appeal protections and that the Departments therefore urge the health plan industry and employers to voluntarily offer external appeals.

Definitions

Recommendation: The Rules' expansive DOL definition of "adverse benefit determination" properly applies to internal claim and appeal processes and the federal external review process, but the definition should also be applied to state external appeal processes. We recommend that this apparent gap in consumer coverage be remedied

through either a technical amendment to Section 2719 of the PHS Act or additional agency guidance that would explicitly include the DOL definition within the scope of the state external review process.

Discussion: The Rules incorporate the DOL definition of adverse benefit determination contained in 29 CFR 2560.503-1 under new agency regulatory sections 26 CFR 54.9815-2719T(a)(2)(i), 29 CFR 2590.715-2719(a)(2)(i), and 45 CFR 147.136(a)(2)(i), respectively.

As defined in the DOL regulations, "adverse benefit determination" means any of the following:

> "a denial, reduction, or termination of, or a failure to provide or make payment(in whole or in part) for, a benefit, including any such denial, reduction, termination, or failure to provide or make payment that is based on a determination of a participant's or beneficiary's eligibility to participate in a plan, and including, with respect to group health plans, a denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit resulting from the application of any utilization review, as well as a failure to cover an item or service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate."

Rescissions of insurance coverage are also included in the terms of the definition under the Rules. However, the Rules appear to apply the DOL definition only in the context of internal appeals and non-grandfathered external appeals that will be handled under a federal review process -- to the exclusion of external appeals under a state review process.

External appeals involving state regulated plans are required to apply the minimum consumer protections contained in the NAIC Model Act including the NAIC definition of "adverse benefit determination," as follows:

> "means a determination by a health carrier or its designee utilization review organization that an admission, availability of care, continued stay or other health care service that is a covered benefit has been reviewed and, based upon the information provided, does not meet the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness, and the requested service or payment for the service is therefore denied, reduced or terminated."

In contrast to the broader DOL definition, the NAIC Model Act definition of adverse benefit determination historically has been limited at the state level to just those appeals involving medical necessity disputes while excluding appeals that apply to coverage denials. However, through its extensive appeal handling experience, MAXIMUS Federal has observed that coverage denials are significantly more prevalent than medical necessity disputes.

Coverage denials arise in many contexts. To better illustrate, here are some typical coverage denial categories and examples of these types of coverage denials that do not involve medical necessity issues:

- **Participant benefit eligibility** – Coverage denials may be issued for services received by an enrollee either before or after the enrollee's effective dates of plan enrollment or disenrollment.

  Example: Mr. Smith enrolled in his group health plan with an effective date of January 1, 2009 and he disenrolled from the plan effective January 31, 2010. Mr. Smith's primary care physician provided services to him on January 15, 2010, and he submitted a claim for payment for these services to the group health plan. The claim was denied on the basis that the plan's computerized recordkeeping system showed that Mr. Smith was not enrolled on the date of service in question.

- **Benefit category eligibility** – Coverage denials may be issued for items or services that do not fall within a covered benefit category.

  Example: Ms. Smith is a 68-year-old female who suffers from alopecia. She has told her group health plan that she lost most of her hair as a result of this condition. She has asked the plan to authorize coverage for a cranial prosthesis. The plan has denied her request. The plan has said that wigs (cranial prostheses) are considered cosmetic in nature and that they do not "promptly repair an injury or improve the functioning of a malformed body member." The plan takes the position that a cranial prosthesis is not a covered benefit under the plan.

- **Appropriate access to out of network care** – Coverage denials may be issued for items or services received by an enrollee when he or she is outside the plan's service area.

  Example: Mr. Smith is a 68-year-old male with a medical history of coronary angioplasty, hyperlipidemia, and hypertension. Mr. Smith saw his in-plan cardiologist on April 1 2009, at which time his doctor prescribed laboratory testing to monitor his blood cholesterol levels. Mr. Smith's cardiologist prescribed these tests after two months, and then again two weeks before his next appointment. Mr. Smith left the plan service area in Texas on June 1, 2009, and went on vacation in Ohio, during which vacation he had the lab work that was prescribed by his cardiologist performed on June 15 2009. Mr. Smith has been billed for this lab work and he has asked the plan to pay for these services. The plan has denied his request. The plan said that these services were not required for a medical emergency or urgently needed care.

- **Exhaustion of benefit limits** – Coverage denials may be issued for items or services received by an enrollee that exceed either an allowed amount or a permissible frequency.

  Example 1: Ms. Smith is a 53-year-old female who suffers from type 1 diabetes mellitus. A durable medical equipment supplier provided her with six units (50 strips per unit) of blood glucose test reagent strips on September 10 2009, and the plan limited payment to two units (or 100 strips) of test strips included in this order. She has been billed for the four units of test strips that were not covered, and she has asked the plan to pay for these test strips. The plan has denied her request. The plan said that her maximum number of

covered test strips (100 strips per month) was paid for and that these four units of test strips exceeded her plan benefit for test strips.

Example 2: Ms. Smith is a 78-year-old female who had a Pap smear and pelvic exam performed on April 1 2007. These services were covered by her group health plan. Since that time, she received a card from her doctor in 2008 reminding her to schedule another such examination. She proceeded to have a screening Pap smear and a cervical or vaginal cancer screening with pelvic and clinical breast examination performed on May 1, 2008. The provider who performed these services used a low risk diagnosis code on the claim submitted to the plan. Ms. Smith has been billed for these screening services. She has asked the plan to pay for these services. The plan has denied her request. The plan said that Pap tests and pelvic exams are only covered once every 24 months for low risk patients.

- **Compliance with health plan policies and rules** – Coverage denials may be issued for items or services received by an enrollee who has not followed prior authorization rules established by the plan.

  Example: Ms. Smith was a 55-year-old patient with undiagnosed but severe and increasing abdominal pain. Following an examination, Ms. Smith's Plan OBGYN told her that he wanted to rule out ovarian cancer. The appropriate first test he recommended was an ultrasound. The physician's staff attempted to refer Ms. Smith to a plan radiologist but an appointment was not available. The staff told Ms. Smith that they checked back with the OB/GYN and that he "recommended" an earlier appointment at a facility that was not within the plan network. Ms. Smith accepted the written referral and kept the appointment. The plan has since denied the claim on the basis that use of an out of plan provider required prior approval by the plan. Ms. Smith contested the denial on the basis that she was willing to use the (unavailable) in plan provider, but then relied upon the specific written referral of her Plan OBGYN. The plan classified the denial as a "coverage" denial because its rationale was related to the prior approval rule and not the necessity of the test.

- **Payment and coinsurance levels** – Payment denials may be issued for enrollee requests that relate to coinsurance, copayments and\or deductibles set forth in the plan contract.

  Example: Mr. Smith is a 55-year-old male who had X-rays taken as part of his pre-operative evaluation prior to knee replacement surgery. He has asked that his group health plan waive his $25 copayment for these X-rays because they were a part of his pre-operative evaluation. The plan has denied his request. The plan said that Mr. Smith has been billed a $25 copayment consistent with the plan contract.

- **Contract interpretation issues** – Coverage or payment disputes may involve different interpretations of plan contract language and its application.

Example: Mr. Smith is a 72-year-old male who had a colonoscopy performed by a plan provider at a regional hospital. The provider billed for this procedure and classified it as a "flexible colonoscopy with removal of tumor(s), polyp(s), or other lesion(s) by snare technique." Mr. Smith has been billed $500 as coinsurance for this procedure. He has told the plan that he believed that he would be having a screening colonoscopy and that screening colonoscopies have a $0 copayment under the plan contract. He has asked the plan to waive any copayment or coinsurance that he might be billed for the colonoscopy. The plan has denied Mr. Smith's request. The plan said that he is responsible for 30 percent coinsurance for outpatient surgery performed at a hospital.

MAXIMUS Federal estimates that 80 percent of the universe of plan denials are related to these coverage questions rather than medical necessity cases and therefore would not be subject to the external state review process according to the existing NAIC model statute definition.

This significant gap in consumer protection is further compounded by the NAIC Model Act provisions regarding how an appeal request can qualify for external review in the first place.

Under the NAIC Model Act process, the claimant (1) submits an appeal request to the state and (2) the state then forwards the request to the plan which (3) performs a preliminary review to determine whether the request qualifies for external review. The Model Act thus puts the plan in the conflicted interest position of determining whether the plan's determination should be challenged in external review. If the plan determines through preliminary review that a request is not eligible for external review the claimant then has to appeal the plan's preliminary review decision to the state. This cumbersome process creates a further disincentive for enrollees to take advantage of the expansive appeal rights that they would be clearly be entitled to under the (broader) DOL definition of adverse benefit determination.

It is noteworthy that the Rule proposes to extent appeal eligibility to rescissions, which heretofore have been considered eligibility or coverage determinations in contrast to the Uniform Model focus on medical necessity. The same compelling policy arguments that result in inclusion of rescissions in external appeals apply equally to coverage appeals.

A final argument in favor of the broader DOL adverse determination speaks to the original rationale for state interest, dating to the 1990s, in establishing IRO external appeals. Specifically, the rationale for IRO external appeal of medical necessity denials is to ensure that the patient is not deprived of medically necessary services. If this occurs the patient is, by definition, subject to a diminution of quality of care, if not a medical harm. Against this goal (patient protection) it matters not at all what the basis for a plan denial is. A patient is equally harmed by the withholding of (medically necessary care) if such care is presumptively denied on a "coverage" argument. Therefore, it is illogical and counterproductive to deprive the patient of an external IRO appeal under circumstances that arise in the majority of adverse determinations (that is, under "coverage" denials).

We take care to point out that our argument to include "coverage" denials in the state appeal process is not a criticism of the overall NAIC model. In fact, it is because we support that model and its efficacy that we propose to expand the scope of disputes that would come before it.

Suggested Regulatory Language

The suggested language would simply be modeled after the scope provisions that appear under the Federal external review process section in the Rules. The applicable section (c) state external review provision in each agency's regulatory section would then read as follows:

> "The State external review process established pursuant to this paragraph (c) applies to any adverse benefit determination or final internal adverse benefit determination as defined in paragraphs (a)(2)(i) and (a)(2)(v) of this section."

Simultaneously, this amendment would require removal of the reference to the NAIC Model Act adverse benefit determination language that currently appears in section (c)(2) (i) of the State external review section applicable to each agency within the Rules. As an alternative, NAIC could contemplate changes to the Model Act so that the definitions are equivalent.

Internal Claims and Appeal Processes (including Notices)

Recommendation: Provide greater flexibility and IRO empowerment in the 24-hour standard.

1. These requirements are described in the rule's preamble and are specifically contained in regulations under Paragraph (b) of 26 CFR 54.9815-2719T, 29 CFR 2590.715-2719, 45 CFR 147.136, respectively. In our view, these are critical consumer protections in addition to the core set of requirements already applicable under the DOL claims procedure regulations at 29 CFR 2560.503-1. The requirements contribute to a more robust internal appeal process that better levels the playing field for consumers. Advances in technology and communications allow for a shortened time frame assuming that the appellant has presented sufficient information to make a decision feasible. In this regard we philosophically support the 24-hour standard; however, we are concerned about the practicality of this standard — not in terms of IRO execution — but rather in terms of meaningful involvement of the patient and compliance by the plan. Here is an area in which the goal of informed participation of the consumer (and physician)—including access to plan material—may work against the goal of timeliness. We prefer the constructions in which the time standards is "72 hours or earlier as dictated by the patient's condition." To the extent an IRO is used for internal review (or in reference to External Review) the regulations should trust the IRO and its medical reviewers to make sound tradeoffs between speed and quality. We note that the technology that the Secretary cites as enabling faster review, actually results not always in early submission of a complete case file, but rather in a sequential and medically appropriate exchange of questions and information between the reviewing physician, the plan and involved providers.

Recommendation: Further define information pertaining to an adverse determination that plans must provide in denial notices and appeal proceedings.

1. Under the Rules, participants appealing an adverse benefit determination may request access to copies of documentation relevant to the claim which must be provided free of charge. The Rules further provide that if a plan considers, relies on or generates any new evidence during the appeal process, or bases its determination on appeal on a new rationale, it must furnish the new evidence or rationale to the claimant as soon as possible and also free of charge. This new evidence could take many forms, and the agencies may wish to consider highlighting some examples to insure that plans and issuers comply with this provision. For example, information about drug utilization review and medical management criteria including references might be appropriate, along with delivery of any secondary evidence relied upon such as a copy or summary of the relevant medical treatment literature. This documentation must be provided sufficiently in advance of the final determination so that the claimant has a reasonable opportunity to respond before the final determination is made. The requirement to automatically provide appellants with new information central to the planned decision is fair and equitable since it provides appellants with an important opportunity to respond effectively to the new evidence or rationale.

Expanded Notice Requirements Provide Participants with A More Informative Explanation of the Decision Rationale and Their Subsequent Appeal Rights.

1. Along with insuring that notices are provided in a culturally and linguistically appropriate manner, expanding the required information to be contained in the notice of adverse benefit determination is another appropriate mechanism that helps consumers understand why their claim has been denied and how they might want to challenge that denial. Some of the additional notice requirements include details about the date of the service, the provider, and denied claim amount (if applicable); the diagnosis code, treatment code and denial code (and their meanings); a description of available internal appeals and external review processes (including how to initiate an appeal); and a statement regarding the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman to assist with claims, appeals and external reviews. We view the consumer advocacy rights contained in the notice as a particularly important resource that participants should be able to easily access. We devote additional commentary on this topic in the next section.

Notices

Appellants should have access to knowledgeable and qualified advocates who can assist appellants throughout the appeal process.

1. Section 2793 of the Affordable Care Act provides that the Secretary shall award grants to eligible States to establish, expand, or provide support for offices of health insurance consumer assistance or health insurance ombudsman programs. The Act envisions that these state offices will assist consumers with the filing of complaints and appeals, provide them with information about the external appeal process, and educate them on their rights and responsibilities with

respect to group health plans and health insurance coverage. These responsibilities are essential because appeal programs inherently are complicated, difficult and time consuming for consumers to navigate. These programs should also facilitate the consumer's ability to use a representative, as well as the right to engage the treating physician in the appeal process. Through creation or enhancement of their consumer advocacy resources, states can insure that consumers will understand and appropriately access the internal and external appeal processes under Section 2719 of the PHS Act.

Easily understood notices and available translations services are integral to the quality of the appeals program. The Rules can be strengthened through additional guidance on the appropriate reading grade level for correspondence and standards dictating when plans and IROs should have translators available to assist plan enrollees.

1. Appellants should receive easy to understand written communications and have access to translations services from **both** health plans and independent review organizations. Section 2719(a)(1)(B) and the Rules require that notices of internal claims and appeals and external review processes must be provided by a plan or issuer in a culturally and linguistically appropriate manner. Numerical thresholds relating to the number of plan participants are specified in the preamble to the rules and instruct plans and issuers when notices in a non-English language are required. In addition to these requirements, consumer protections would be furthered if all denial and appeal related communications from both health plans and IROs are written no higher than an 8th grade reading level, and if plans and IROs have translators available to assist enrollees in a non-English language when the percentage of participants literate in the same non-English language exceeds the thresholds stated in the Rules. Similar requirements presently exist in a number of Federally funded programs and assist in ensuring consumers are provided a full understanding of their rights and responsibilities throughout the internal and external appeal processes.

Notices should be strengthened to provide appellants with the full range of appeal rights they are entitled to.

1. The notices recently issued on the OCIIO website should be strengthened to include important safeguards and information that enrollees need to properly understand and pursue their appeal rights. For example, although there is a reference about the opportunity to have a representative file an appeal on behalf of an enrollee, the notice should go further and emphasize that appellants have the ongoing right to be represented by a third party at all stages of the appeal process (internal and external). Moreover, there may be occasions when an appeal is deemed incomplete by the plan, issuer or IRO. The notice should inform appellants that they may receive additional correspondence informing them about the insufficient information and provide them with an opportunity to provide it by a reasonable deadline. In addition, the Departments should consider requiring plans and issuers to provide enrollees with acknowledgment notices signifying receipt of the correspondence and providing appellants with peace of mind that their arguments have been received and are being considered. Finally, although we firmly take the position elsewhere within these comments about the need to have external appeals apply to both grandfathered and non-grandfathered plans, should the grandfathered plan exemption remain,

plans should characterize their grandfathered status in the notice of adverse determination so appellants will know whether they have further appeal right they may wish to pursue.

State Standards for External Review

Conflict of Interest Standards for Independent Review Organizations (IROs) should be strengthened and better enforced.

1. Under the standards of Section 2710 of the PHS Act, IROs must be independent. However the Rules do not specifically preclude conflicts of interest that exist today. Unfortunately, some of these conflicts are also permitted under existing IRO accreditation standards. Consequently, it is important the Department itself further define and preclude conflicts at the external review level.

A. Precluding Financial Relationships between the External IRO insurers or health plans

Under current standards, an organization that otherwise qualifies as an external IRO may have business relationships with the health plans that it reviews. One common example is found in IROs that sell "internal" appeal or review services related to initial determinations. We do not oppose these necessary relationships. However, the very fact that an IRO has a contractual relationship and earns revenue from an insurer or plan constitutes a direct conflict if that IRO undertakes an external review for that plan. This form of conflict exists if the IRO entity sells any other services to the health plan (for example, consulting, appeal process consultation, and so on). The Department's rule should define contractual relationships between an IRO and a health plan as a direct conflict with respect to external review. Further, the Department should not permit "mitigations" of this conflict.

B. Assessing Conflict with respect to IRO Parent Organizations

Some IROs are legal subsidiaries or divisions or parent corporations. As such, they are controlled by the parent corporation irrespective of organizational firewalls, "independent" managers and the like. In apply conflict standards, the Department and States should evaluate not only the IRO entity conflicts, but that of the parent. Direct conflicts of the parent, such as noted above, should be attributed to the IRO subsidiary and should not be subject to mitigation.

It has been argued that while such conflicts exist, they must be tolerated or there will be an inadequate supply of IROs for external review. This is not valid argument, but it is a self fulfilling prophecy. URAC reports that there are over 40 IRO organizations and it expects many more to seek accreditation. If stronger conflict standards are applied to external IROs, the market will quickly adjust and many IROs dedicated to external review will emerge and thrive. If these standards are not applied, IROs have no incentive to adopt stronger conflict policies with respect to external review.

C. Precluding Conflict vis-à-vis Regulators

We accept and support the fact that Regulations—whether federal or state—have the responsibility to competitively select IROs and closely monitor their performance to ensure compliance with all external review standards. In addition to relying upon IRO accreditation, regulators can and should engage in such oversight as IRO site visits, review of policies, validation or timeliness and sample review of completed cases. If an IRO does not perform, regulators can initiate corrective action up to and including termination. The Medicare QIC program exemplifies an appeal model in which the regulator (CMS) is actively involved in oversight and quality improvement, but appropriately stops short of influencing active case decisions.

However, the policies and practices in some jurisdictions result in direct regulator participation in active external review cases. For instance, some regulators dictate the specialty and qualifications they expect a physician reviewer to have during case assignment and may approve or reject specialists who meet all credentialing and other standards. Regulators have defined the "issues for review" in a case or have challenged the decision an IRO physician reviewer has made. Some regulators have objected to the decision (uphold or overturn) of the independent IRO and ordered a subsequent review.

Under the NAIC Uniform Model Act and under most federal appeal contracting programs, the regulator selects the IRO because it is the accredited entity with independent expertise to make external review decisions. It is noteworthy that in many jurisdictions the decision to vest decision making responsibility in the IRO has been specifically made by the legislative body.

Consequently, we believe the Departments should include a prohibition against regulator intervention in cases except in obvious cases of neglect or impropriety.

Recommendations for Minimum Standards for State External Review

1. Within the Overview of the Rules the Departments invite comments of the list of 16 consumer protections and whether further elements of the NAIC Model Act should be included in the list. The list of 16 consumer protections is a very good starting point to ensure an effective state external review programs that could be strengthened in the following areas.

   a. To the extent possible within the statute, the regulation should preclude an insurer or plan from making a determination about the eligibility of a case for external review. This is an inherent conflict and potential barrier to appeals. It would be preferable to require all cases to be submitted to the IRO which should be empowered to make such eligibility determinations.

   b. To the extent possible within the statute, the regulation should require that upon completion or exhaustion of the "internal" appeal, any case which has not be founded in full favor of the enrollee should be automatically forwarded by the plan for external review. This process is long and well established in the Medicare Part C appeals

program. Requirements for the consumer to separately request an external appeal place an unnecessary burden on the consumer,

c. The list indicates a state may require a nominal filing for the claimant requesting an external review and that to be considered a filing fee must not exceed $25. This is another deterrent to consumer utilization and also creates administrative burdens (and appeal processing delays) upon both the consumer and the IRO. The fact that the filing fee is "nominal" indicates that it serves no real purpose in offsetting the cost of the appeal program. The sole rationale for such a fee is to deter "frivolous" appeals. However, the low rates of external appeals indicate that such filings are not common.

d. As discussed above, the Department should stipulate additional and necessary conflict of interest standards.

e. The list indicates that if an enrollee submits additional information to the IRO, the IRO must submit this information to the plan for the plans consideration. In many instances the information provided by a claimant is duplicative of information already considered by the plan or is, frankly, not relevant. However, the requirement to provide this information to the plan for its review adds time and cost and may result in a response from the plan which itself must or can be shared with the consumer. We recommend that the IRO be given the discretion to determine if newly submitted information is relevant and should be reviewed by the plan. .

f. The list indicates standard reviews should be completed within 45 days after the receipt of the request for external review. The majority of existing state and federal external review programs require standard pre-service appeals to be completed in 30 days or less. In addition, claimants have generally gone through multiple months of appeals at the plan level by the time they reach the external review level. Therefore, in order to provide claimants the most expeditious resolution of standard appeals, states should require standard pre-service appeals be completed in 30 days or less of receipt of complete case file information.

g. A number of states select external IROs via a careful competitive bidding process, ensure that the external IRO has no conflicts, negotiate to reduce price and then depend on a single contractor, or a single contractor with back-up. So long as the contracting process used by the states meets these and other relevant standards, the Department should not arbitrarily require select of three (or more) IROs, nor to randomly rotate cases across IROs.

Further sections of the NAIC Model Act could be enhanced to ensure the most efficient and effective state external review process.

1. Section 4 of the Model Act indicates the Act shall not apply to a number of insurance policies and/or certificates including dental, hospital indemnity, and long-term care insurance. Certain states already include dental and long-term care insurance. This language discourages

other states from adopting external review for other insurance programs and is inconsistent with the Departments' recommendation that state external appeal programs should be "market-wide" and include all insurance issuers (see below for further discussion on this topic). As such, the Departments should continue to encourage states to engage in market-wide inclusion for their external review programs.

2. Section 7 of the Model Act only allows for an enrollee to avoid exhaustion of a plan's internal grievance process only in significantly limited circumstances. This is not a consumer protection and is inconsistent with the Departments' requirement that a plan offering individual coverage should only have one level of appeal, the Departments should instruct all plans to have only one level of appeal or allow enrollee's the opportunity to elect external review after the first level plan appeal.

3. Section 8 and 9 of the Model Act address standard and expedited external reviews related to medical necessity and makes plans responsible for determining appeal eligibility. As set forth above, this is a conflict as it allows the plan to determine what is eligible for an independent/ external review. To avoid this conflict all eligibility determinations should be made by the state or the IRO.

Federal External Review Process

IROs should be defined as exempt from fiduciary status when handling appeals under the Federal external review process described in the Rules and DOL Technical Release 2010-01. The DOL should provide additional guidance that explicitly describes the IRO's function as not being equivalent to that of a fiduciary under ERISA.

1. Historically, IROs that contracted with self-insured plans to provide external review services had not been considered plan fiduciaries under ERISA. Based upon the Rules, there is a concern that an IRO would or could be considered a fiduciary since the Rules describe that IROs will review claims de novo and make binding coverage determinations without deference to any decisions or conclusions reached during the plan's internal claims and appeals stage. The concept of an IRO independent of the plan while simultaneously being considered a plan fiduciary will create a great deal of confusion associated with the external review process for all stakeholders and could potentially impinge upon the IROs independence. There is a distinct possibility that many IROs would not want to participate in the external review process of self-insured plans if there is a potential of being considered a fiduciary. Of perhaps greater significance is the potential that in acting in fiduciary role to the plan, the IRO would not be totally independent. To avoid these issues and ensure as clear and efficient process as possible, DOL should set forth clear and convincing guidance that IROs providing external review services for self-insured plans are not considered fiduciaries under ERISA.

States and other regulators should be required to use competitive contracting to select one or more IROs under the NAIC Model Act and in accordance with the interim final regulations implementing section 2719 of the PHS Act, but should not be required to randomly rotate cases across an arbitrary number of IROs.

1. Technical Release 2010-01 provides that in order for self-insured plans to fit within the interim safe harbor they must either voluntarily comply with an applicable existing state process or contract with a minimum of three IROs. Both of these alternatives create issues for self-insured plans and concerns with regard to conflict of interest. In addition, discussions with self-insured plan representatives reveal that neither of these alternatives is preferred. Voluntarily complying with an existing state process is difficult for many self-insured plans as many plans cover a multi-state region. Under this alternative, plans could be in the position of complying with numerous different state requirements and could be providing inequitable remedies for their employees who reside in different states (for example, some existing state programs allow for external benefit and coverage denials while other states only allow for external review of medical necessity and experimental denials). Furthermore, plans are unclear on which state programs they would be required to comply with (for example, if the administrator of a multi-state plan is located in the state of Michigan -- is the safe harbor met if all appeals subject to the existing Michigan review process or will appeals be subject to the existing state process in which each enrollee resides?). This becomes further complicated if a multi-state plan has enrollees in states that do not have an existing process, as a subset of enrollees could be subject to yet a different external review process altogether.

To avoid the issues attendant with both of the above frameworks, the contemplated "federal process" should employ an IRO contracting model such as the Medicare Qualified Independent Contractor (QIC) program. In this model, IROs are selected on a transparent competitive basis without any involvement of plans in the selection or payment process. In addition, this format will provide plans and enrollees a single understandable program that is efficient in both process and cost and that will ensure all enrollees are provided access to the same appeals program. With regard to cost, it should be noted that during the history of the QIC program, costs for appeals have decreased during each contract cycle.

Conclusion

We thank the Departments for their consideration of our comments and for the monumental work completed to date. For any questions or further information required please contact:

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