

September 21, 2010



**BlueCross BlueShield
Association**

An Association of Independent
Blue Cross and Blue Shield Plans

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The Honorable Phyllis C. Borzi
Assistant Secretary, Employee Benefits Security Administration
U.S. Department of Labor

Jay Angoff
Director, Office of Consumer Information and Insurance Oversight
U.S. Department of Health and Human Services

The Honorable Michael F. Mundaca
Assistant Secretary of the Treasury
U.S. Department of the Treasury

Submitted via the Federal Rulemaking Portal: <http://www.regulations.gov>

**Re: Interim Final 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 (RIN 1210-AB45)**

Dear Secretary Borzi, Director Angoff, and Secretary Mundaca:

The Blue Cross and Blue Shield Association (“BCBSA”) – representing the 39 independent Blue Cross and Blue Shield “Plans” that collectively provide health coverage to nearly 100 million, or one in three Americans – appreciates the opportunity to submit comments on the Interim Final Rules (the “Rule”) 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 (ACA) as issued in the *Federal Register* on July 23, 2010 (75 Fed. Reg. 43330).

BCBSA commends the Departments for recognizing that by making claims and appeals processes more uniform, there will be efficiency in the operation of employee benefit plans and health care delivery. Moreover, we agree with the Departments that reducing the complexity that arises when different market segments are subject to varying claims and appeals standards will increase efficiency in the operation of employee benefit plans and health care delivery as well as health insurance and labor markets.

BCBSA also expresses appreciation for the enforcement grace period set forth in Technical Release 2010-02, and for the clarifications provided in the frequently asked questions (FAQs) on the external review interim compliance period set forth in Technical Release 2010-01. BCBSA and its Plans were concerned they would not have enough time to make

the changes required by additional standards that were not anticipated, in particular standards for (1) the timeframe for urgent care claims; (2) linguistically appropriate notices; (3) diagnosis and procedure codes in notices; and (4) strict adherence. We are extremely pleased the Departments provided an enforcement grace period until July 1, 2011 so that Plans can continue to work in good faith to implement these additional standards. We would also like to thank the Departments for the useful clarification regarding the interim compliance period for external review set forth in Technical Release 2010-01 for self-funded plans.

Even with the above, implementing the Rule as published will be challenging. One area of concern is that the Rule appears not to meet the objective laid out in the preamble of having similar claims and appeals standards for different market segments. For example, the Rule will result in consumers covered by fully-insured or non-ERISA self-funded plans being subject to one set of standards regarding the scope of external review, and consumers in ERISA self-funded plans another. Also, the scope of standards for state and federal external review processes go beyond the NAIC Uniform Model Act.

BCBSA believes that streamlining requirements that go beyond current Department of Labor (DOL) procedures and the NAIC Model Act – including the additional requirements covered under the above-mentioned Technical Releases – will lead to efficiency gains and improvements in certainty and consistency. Such gains and improvements will benefit consumers, providers, employers, and health plans.

Our comments are organized into three sections where we offer BCBSA's recommendations to: 1) Ensure the Rule meets the underlying objectives of consistency across market segments; 2) Streamline certain requirement to create efficiencies; and 3) Clarify certain requirements.

* * *

I. ENSURING REQUIREMENTS MEET UNDERLYING OBJECTIVES

The preamble to the Rule emphasizes that greater certainty and consistency in handling benefit claims and appeals – avoiding varying claims and appeals standards for different market segments – will increase efficiency in plans and health care delivery. BCBSA strongly agrees with this statement. However, the Rule does not follow this premise as it varies the scope of external review for different market segments and also goes beyond the NAIC Model Act and many state external review laws.

State External Review Scope

Issue. The Rule directs that state external review processes include, at a minimum, the consumer protections of the NAIC Uniform Model Act. One of these minimum standards is that external review shall apply to “adverse benefit determinations. . . that are based on the issuer’s (or plan’s) requirements for medical necessity, appropriateness, health care setting, level of care, or *effectiveness of a covered benefit* [emphasis added].” However, the term “effectiveness of a covered benefit” does not appear in the NAIC Model Act. Under the NAIC model act, health plan members may appeal denials based on medical necessity,

appropriateness, health care setting, level of care, or effectiveness of the health care service or treatment [emphasis added].

Use of the term “effectiveness of a covered benefit” (if it was intended) could be interpreted to widen the scope of external review beyond the NAIC Model Act to cover denials based on benefit or coverage determinations. For example, the regulation could be read to permit a plan participant to demand external review of a contractual limit on physical therapy visits, even if that limit is part of the definition of essential health benefits, by arguing that the benefits provided by the plan were “not effective.” A plan participant could appeal a requirement to use a network provider when covered benefits are available only through network providers. These types of appeals are not in the nature of appeals that are reviewable externally under the NAIC model nor in most states with external review laws today. Thus, this term is more expansive than the NAIC Model Act – and most state external review laws – that it will greatly increase complexity, reduce efficiency, and raise costs.

Recommendation: Revise the Rule to use the same language of external review scope in the NAIC Model Act for state external review processes – replace the term “effectiveness of a covered benefit” with “effectiveness of the health care service.”

Federal External Review Scope

Issue. ACA directs the Secretary to develop “an effective external review process that meets minimum standards” similar to the NAIC Model Act. However, the Rule requires a much wider scope of external review in the federal process than in the NAIC Model Act or in the new requirements for the State external review process. State external reviews are limited largely to denials based on medical necessity that involve issues of clinical judgment, whereas federal reviews are allowed for any adverse benefit determination (except eligibility denials), which under current DOL interpretation includes claims determinations, denials based on benefit and coverage determinations (e.g., the deductible amount applied by the plan) where the member is paid at less than 100% of what was claimed and the member bears liability, as well as medical necessity.

Expanding the scope of external review to cover denials based on benefit or coverage determinations is more expansive than the NAIC Model Act – as well as most state external review laws – and will increase complexity, reduce efficiency, and raise costs.

Recommendation: BCBSA requests that the Departments modify the Rule to conform federal external review to the same scope as state external review, modified to use the same language as the NAIC Uniform Model Act.

II. STREAMLINING REQUIREMENTS

Allowing additional time to implement new standards will help Plans meet their compliance obligations. However, these standards, along with other requirements, are complex, requiring significant time and resources to implement. Therefore, BCBSA offers recommendations for streamlining these requirements.

Including Codes in Notices

Issue. The Rule requires new content requirements for notices of adverse benefit determinations to include “information sufficient to identify the claim involved.” In addition to date of service, the health care provider, the claim amount (if applicable), the reason(s) for the adverse benefit determination, the denial code, and a description of the plan’s standard, the notices must also include diagnosis code(s) and treatment code(s) and their corresponding meanings.

Currently, the main way in which plans communicate adverse benefit determinations in the post-service context is through issuing Explanation of Benefits (EOB) statements. No BCBS Plan includes diagnosis codes in EOBs. (We would also note that including diagnosis and procedure codes and their corresponding meanings goes beyond the requirements in Medicare: the notices issued by Medicare Advantage Plans are not required to include this information; and the Medicare Summary Notices in fee-for-service Medicare that are the Medicare equivalent of EOBs include procedure codes – without corresponding meanings – for outpatient services, but not for inpatient services, **and no diagnosis codes.**)

The benefit to consumers of including diagnosis and treatment codes in ensuring the clear identification of a claim – in light of all the other information included in the notice – is likely to be small to non-existent. No BCBS Plan is aware of any problem in identifying what to appeal in the absence of these codes. Yet the costs of including diagnosis and treatment codes will be substantial. The system changes needed – reprogramming internal system formats, file structures, and processing logic to generate the codes from existing data repositories and map them onto EOBs and other notices, reconfiguring EOBs, and then testing and debugging – and subsequent internal training would, under the best of circumstances, take six to ten or more months. Moreover, including diagnosis codes could confuse consumers because frequently the diagnosis codes do not line up with information in the medical record, as when physicians label tests with the disease they hope to rule out.

The ongoing implementation of the upgrade to the 5010 version of the HIPAA transactions and the transition to ICD-10 will increase implementation time from the six to ten month range to one year or more. One reason is that the same IT specialists who would reprogram systems to capture diagnosis/procedure codes are already working on 5010 and ICD-10 and they cannot do everything at the same time. A second reason has to do with the system instabilities caused by the upgrade to version 5010: a basic tenet of systems design is to implement and test one major systems change at a time. Since plans are in the middle of implementing the version 5010 transaction standards, the “platform” from which plans would need to extract diagnosis and procedure information to map onto EOBs is unstable. Therefore, systems experts expect that a higher-than-normal rate of errors will occur and, hence, a longer process of testing, debugging, and testing again.

Two other factors would add considerably to the time and cost of including diagnosis and treatment codes.

- First, claims are often submitted with multiple diagnosis codes and treatment codes. Nothing in the Rule would necessarily permit plans to list only the primary diagnosis code and limit the number of treatment codes. Mapping every single diagnosis and

treatment code onto the EOB or other notices would result in lengthy and potentially confusing documents.

- Second, the definitions for the 13,000 ICD-9-CM diagnosis codes (soon to become 68,000 ICD-10-CM codes) included in ICD codebooks are frequently not understandable to most consumers. Receiving, for example, an EOB that describes ICD-9-CM code 277.7 as “Dysmetabolic syndrome X,” or 202.58 as “Letterer-Siwe disease, Acute: histiocytosis X (progressive)” may not help the member. Opaque meanings are more likely to confuse than to clarify. Crafting understandable meanings for thousands of codes – not to mention programming and fitting those definitions into EOBs – will take considerable time.

Finally, we would note that including diagnosis and treatment codes will invariably raise serious privacy concerns. If the postal service today delivers an EOB to the wrong address, at most the unauthorized recipient will glean some fairly generic information about the patient (e.g., my neighbor had an office visit and a lab test on such and such a date). The Rule as published would potentially inform unauthorized recipients that their neighbor had a substance abuse problem, or HIV, or some other sensitive condition.

Privacy concerns will arise even within the family when, for example, one family member opens the EOB mailed to another family member in the same household and discovers information that the other family member would prefer to have kept confidential.

This scenario not only underscores threats to one’s privacy, it also raises additional compliance costs for plans because such disclosures may be a breach under Section 13400(1)(A) of the Health Information Technology for Economic and Clinical Health (HITECH) Act when an unauthorized recipient (e.g., a father) receives an unauthorized disclosure of protected health information that compromises the security or privacy of another family member’s protected health information. Plans that today send EOB statements to subscribers will need to address statements to individual members, thus increasing data collection, paper, and mailing costs. Plans can expect increased requests or complaints from members regarding disclosure and increased requests for restriction of disclosure.

Moreover, a federal requirement to include diagnosis codes would likely preempt the many state laws that impose more stringent requirements for disclosure of PHI (regarding conditions such as mental health, chemical addiction treatment, pregnancy, birth control, HIV/AIDs) than the HIPAA Privacy Rule. For instance, under Indiana law, “medical or epidemiological information involving a communicable disease” [which includes HIV/AIDS and other STDs] cannot be disclosed without the individual’s consent.¹

Recommendation: BCBSA appreciates the enforcement grace period granted by the Departments for the additional requirements for notices, which include diagnosis and procedure codes. However, we respectfully request that the Departments remove diagnosis and procedure codes and their corresponding meanings from the list of data elements required in notices of adverse benefit determinations.

¹ March 31, 2009: Health Information Security and Privacy Collaboration Final Report of the Interstate Disclosure and Patient Consent Requirements Collaborative Prepared for RTI International

As an alternative, BCBSA recommends that the Departments permit plans to make primary diagnosis and procedure codes – and not the secondary diagnosis codes – and corresponding meanings available upon request. Further, we request that the Departments clarify that when the diagnosis is sensitive or serious, and the member inquiring appears to be unaware of the diagnosis, the plan would have the flexibility to help the member obtain the information from the provider. A plan would not want inadvertently to cause distress to the member by disclosing diagnostic information that the member's physician has not yet discussed with the member.

This alternative approach would still take considerable time and effort to implement, but it would be less time-consuming, less costly, and less invasive of individuals' privacy.

Finally, BCBSA requests that the Departments clarify that even upon request, plans may not be able to provide diagnosis or procedure codes for pharmacy claims because such information is typically not included on pharmacy claims.

“Linguistically appropriate” Requirements

Issue. The Rule requires that plans provide notices in a “culturally and linguistically appropriate manner”. As issued in the Rule, plans must include in all notices a statement in a “threshold” non-English language that all subsequent notices, communications, and oral assistance will be available in that non-English language.

The method for determining threshold languages differs between individual and group markets. For the individual market, a threshold language is one in which 10% or more of the population in the claimant's county is literate in the non-English language. For the group market, if the group covers fewer than 100 participants at the start of the year, a threshold language is one in which 25% or more of all plan participants are only literate only in that language; if the group covers 100 or more participants, the lesser of 500 plan participants or 10% or more are literate in that language.

The group market methodology is based on the current DOL requirements for Summary Plan Descriptions (29 C.F.R. § 2520.102-2). However, under the SPD rule, plans with significant numbers of non-English speaking participants must include a notice in the summary plan description (written in English) offering them assistance, and “The assistance provided *need not involve written materials* [emphasis added], but shall be given in the non-English language common to these participants and shall be calculated to provide them with a reasonable opportunity to become informed as to their rights and obligations under the plan.” The SPD rule gives the following as an example of such as statement:

“This booklet contains a summary in English of your plan rights and benefits under Employer A Pension Plan. If you have difficulty understanding any part of this booklet, contact Mr. John Doe, the plan administrator, at his office in Room 123, 456 Main St., Anywhere City, State 20001. Office hours are from 8:30 A.M. to 5:00 P.M. Monday through Friday. You may also call the plan administrator's office at (202) 555-2345 for assistance.”

In contrast, the Rule requires that plans offer those literate in a non-English language a much more extensive and rigorous amount of assistance: upon request, all

subsequent notices must be in the non-English language – and in an appeals process, notices must be tailored to the unique circumstances of each claimant, unlike SPDs that are “one-shot” documents – and a plan’s customer assistance process (such as a telephone hotline that may be manned on a 24/7 basis) must answer questions and provide help in the non-English language. Moreover, whereas an employer has only one group of plan participants, a plan may have tens of thousands of employer groups. Thus, the Rule goes well beyond the SPD requirements.

The Departments believe that the overall costs of this requirement will be small because only a small number of plans would be affected. However, because the threshold languages are determined at the plan (employer group) level, the impacts could be substantial because if even one small group were to meet the threshold criterion, then the plan would have to have systems and procedures in place to meet all of the extensive and rigorous linguistically appropriate requirements. Especially in areas that are home to many immigrant and ethnic groups, this new requirement could impose enormous costs. For example, 92 languages have been specifically identified among students in the Los Angeles public school system. If a plan serving LA were to issue policies to 92 small businesses run by families representing each of those 92 languages, and within each business at least 25% of plan participants were only literate in that non-English language, then the plan would have to add 92 statements to the EOB in the non-English language, find and train customer service agents for each of the 92 languages, and perhaps translate every notice into 92 languages.

Thus, the new requirement for “linguistically appropriate” notices and assistance could require plans to get translations for multiple languages for multiple forms and notices, and to develop the capability to respond to requests for assistance in many different languages. Moreover, the cost of determining even which threshold languages exist could be high because this is not information that health insurance issuers collect today and they will need to rely on the plan administrator to gather that information and provide it to the issuer.

It is also worth noting that the Rule is wider and less flexible than the linguistically appropriate requirements adopted in California (CA), the most far-reaching non-English standards adopted by any State. CA defines threshold languages based on the size of the plan’s/insurer’s enrollment, not on an individual employer plan-by-employer-plan basis. CA law also provides for some flexibility as to how to gather the information, and whether to make language assistance available in writing or orally, which improves the feasibility of collecting language information. Plans/issuers must survey the language preferences and needs of their entire enrollee population; if the plan/issuer has one million or more enrollees, the threshold languages are the top two non-English languages as determined by the assessment plus any other language indicated in the assessment by the lesser of 15,000 enrollees stating a language preference or 0.75% of the enrollee population.

As a result of CA’s more reasonable approach, a BCBS Plan serving CA determined that it must make translated documents available in five languages – instead of the 92 theoretically possible under the Rule – and it must make oral translation assistance available in additional languages, which can be done at a reasonable cost compared to translating written documents. It is worth noting that the CA law gave plans/issuers one year to comply with a language requirement that is narrower and more flexible than the language requirement incorporated in the Rule.

Recommendation: BCBSA appreciates the enforcement grace period that the Departments established for the additional requirement for linguistic appropriateness. However, BCBSA requests that the Departments consider streamlining the “linguistically appropriate” requirements to reduce their impact on costs and improve administrative efficiencies by:

- Allowing plans to use an alternative methodology to determine the threshold non-English languages for the group market, such as by (1) surveying the entire population of participants in the state in which the claimant lives, or (2) by adopting the geographic-based methodology required for the individual market – if able to use census results to identify threshold languages, plans would be able to develop common informational “taglines” for all EOBs and appeals correspondence for individuals and groups, thus removing the costly requirement of managing to a group customer’s census.
- Directing plans to follow the wording of the SPD requirements by noting in their statements to participants that any language assistance provided “need not involve written materials, but shall be given in the non-English language common to these participants and shall be calculated to provide them with a reasonable opportunity to become informed as to their rights and obligations in appealing an adverse benefit determination.” Plans would still have the option of translating some written materials into a foreign language. Taking advantage of this more streamlined and flexible approach, plans also could have open benefit meetings for family members since younger family members are likely to be more fluent in English, or have bilingual or separate meetings (in person or webcast) in another language.
- Deeming a plan that follows a state requirement that is substantially similar to the Rule’s requirement as in compliance with the federal requirement. Otherwise, the state and federal requirements may be just different enough that a plan in that state (as in CA) would have to meet two sets of rules simultaneously.

Non-Compliance Standard

Issue. The Rule sets a standard of strict adherence: a claimant will be deemed to have exhausted the internal claims and appeals if the plan fails to follow the Rule strictly. This holds even if the plan has substantially complied with the requirements, or has committed an error that the Rule refers to as “de minimis.”

ERISA regulations already include a provision under which failure to establish and follow minimum procedures would result in a finding that a claimant “shall be deemed to have exhausted the administrative remedies available under the plan.” A subsequent Department of Labor (DOL) FAQ explained that any mistakes processing a claim or an appeal that do not prejudice a participant will not justify a participant proceeding directly to court without exhausting the plan’s claims procedures.

As explained in the attached legal memorandum, the courts generally follow the DOL FAQ carefully in examining a plan’s compliance – they have adopted standards to ensure substantial compliance with claims procedures so that any mistakes in compliance do not

prejudice participants and beneficiaries. Therefore, a standard of strict adherence appears to be a solution searching for a problem.

Since a standard of strict adherence does not permit any analysis of whether a plan's error prejudices a participant, even minimal or trifling errors will trigger "deemed exhaustion" of the administrative process and de novo review by the district court – leading to more litigation, and more expensive litigation, over benefit claims.

Recommendation: BCBSA appreciates the enforcement grace period that the Departments established for the additional requirement for strict adherence. However, to constrain implementation and legal costs, BCBSA requests that when the grace period ends, the Departments replace the "strict adherence" standard with a "materiality standard."

Independent Review Organizations

Issue. DOL Technical Release 2010-01 sets forth procedures for a federal external review process that plans may follow to take benefit from an interim enforcement safe harbor. However, plans will be unable to take advantage of the safe harbor within the short compliance timeframe because of challenges in contracting with at least three, accredited independent review organizations (IROs).

- First, in many parts of the country no more than one or two IROs are currently in operation. Although, as noted in the DOL's FAQs, the IRO is not required to be in the same state as the plan, 44 states and the District of Columbia have established extensive application requirements for an accredited IRO to seek licensure. Thus, plans may not be able to contract with IROs that are not licensed to practice in the plan's state. Moreover, various states require that the physician who conducts the independent review must be licensed where the patient resides, further restricting plan opportunities to contact with IROs.
- Second, since most state external reviews follow the NAIC Model Act by limiting reviews to denials based on medical necessity, and the Rule goes further by allowing review of coverage denials, the existing IROs will need time to hire or contract with legal experts to make coverage determinations (assuming that the Departments do not revise the Rule as recommended under Section I).
- Third, contracting between plans and IROs will be an exacting, time-consuming process because IROs – who receive protected health information from plans – must be treated as HIPAA business associates (BA): the HITECH Act significantly raised the regulatory requirements placed on covered entities and business associates.

Recommendation: BCBSA appreciates the clarification expressed in the DOL's FAQs that a plan that does not satisfy all the standards of the Technical Release's safe harbor may in some circumstances nonetheless be considered to be in compliance, to be determined on a case-by-case basis under a facts and circumstances analysis. We believe it would be more efficient to have a safe harbor that is workable because that would limit the burden on plans and on DOL of undertaking a facts and circumstances analysis. Therefore, we request that the Departments amend the Technical Release to allow plans to contract with one (1) IRO that meets all the conditions for participation. Further, we request that the Departments extend the safe harbor to plans that make a good faith effort to contract with an IRO, but are

simply unable to because no IRO has the capability (because of lack of license or lack of needed legal experts) to perform any or a particular type of external review.

Independent Review Organizations

Issue. Technical Release 2010-01 Section A(4) requires that upon receiving a notice of a final external review decision reversing the plan's adverse benefit determination, the plan immediately must not only provide coverage but also immediately pay benefits for the claim. The requirement to immediately pay benefits is not in the NAIC Model Act, which states:

“(I)(3) Upon receipt of a notice of a decision pursuant to paragraph (1) reversing the adverse determination or final adverse determination, the health carrier immediately shall approve the coverage that was the subject of the adverse determination or final adverse determination.”

Requiring immediate payment is not only a departure from the NAIC Model Act, it also would impose an unnecessarily heavy administrative burden on plan's financial systems. To put this in context, under current CMS guidance, the Medicare fee-for-service claims processing contractor has 30 days subsequent to appeals' decision date to effectuate the claim for a reversed/ favorable decision.

Recommendation: BCBSA has no problem with immediately approving the coverage – thus lifting any liability concerns from the patient – but requests that DOL establish a more reasonable, 30-day timeframe for paying the claim, the same as is required of Medicare contractors.

Full and Fair Review—New Evidence

Issue. The Rule requires plans to provide any new or additional evidence considered, relied upon, or generated in connection with a claim, or any new or additional rationale in advance of final notice of adverse determination on review to allow claimants opportunity for response. Such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on review is required to be provided to give the claimant a reasonable opportunity to respond prior to that date. If the claimant responds to the information provided, plans will need to review and respond to the claimant, for all practical purposes creating another level of appeal (within a rigid timeframe).

Further pressuring time is the requirement that many states have for a two-level internal appeals process. If a fully-insured plan offers two levels of appeal, both must be offered within the Rule's timeframe. Layering on additional time to allow claimants to respond prior to the turnaround time deadline will strain an already compressed timeframe by adding what is for all intents and purposes a third level of appeal.

Recommendation: BCBSA recommends that the Departments streamline the review process by either (1) requiring that plans provide new or additional evidence upon request (consistent with the current DOL rule); or (2) provide subregulatory guidance around what constitutes “new or additional evidence” and set a time threshold to reduce administrative burden: e.g., if the new information is not obtained prior to 10 days before the deadline to respond, then the plans can include information with the final internal adverse determination.

III. AREAS THAT NEED CLARIFICATION

Testimony

Issue. The Rule requires that plans allow claimants to present evidence and testimony as part of the internal claims and appeals process. The word “testimony,” which appears in the statute but not in the DOL claims procedures, is ambiguous: it could be construed to mean oral statements given under oath by a witness in answer to questions posed by attorneys at a deposition or evidentiary hearing; or it could be construed to be consistent with the current claims procedures that give claimants the opportunity to submit written comments, document, records, and other information relating to the claim for benefits.

Recommendation: In keeping with the Departments’ belief that the additional requirements “merely clarify provisions of the DOL claims procedure regulation,” BCBSA requests that the Departments clarify that “testimony” has the meaning that is consistent with the opportunity provided in the current DOL claims procedures to submit written comments, documents, records, and other information relating to the claim for benefits.

External Review Criteria

Issue. Technical Release 2010-01 establishes external review procedures for interim compliance. The Release notes: “These procedures are based on the Uniform Health Carrier External Review Model Act promulgated by the [NAIC]. . .” However, in setting out the criteria for the independent review organization (IRO) to reach a decision, the Rule diverges from the Model Act by directing the IRO to consider “appropriate practice guidelines;” the NAIC Model Act directs reviewers to consider “*the most* [emphasis added] appropriate practice guidelines.” By eliminating “the most,” the Rule could be construed as lowering the burden of proof for the reviewer’s rationale for its decision; that is, it is easier to claim that one’s decision is based on “appropriate” guidelines than to claim that one’s decision is based on “the most appropriate” guidelines.

Recommendation: Because the Release’s procedures are based on the NAIC Model Act, BCBSA requests that the Departments clarify either that (1) dropping “most appropriate” was inadvertent, and that term will be added back; or (2) that the Departments still intend that reviews consider “the most” appropriate guidelines.

Linguistically Appropriate Notices

Issue. The Rule states that once a claimant has requested a notice in a non-English language, the plan must “provide all subsequent notices to the claimant in the non-English language.” This assumes that claimants will always want all of their subsequent correspondences in the language of their choice. However, it is possible that the claimant only requested a particular letter to be translated because of the technical language it contained or for a better understanding of that component.

Recommendation: If the Departments do not adopt the recommendations made under Section II – and continue to require that plans provide notices in non-English languages – BCBSA requests that the Departments clarify that plans may ask claimants to specify

whether they are requesting a specific notice or defined set of notices in the non-English language, as opposed to all subsequent notices.

* * *

We appreciate your consideration of our comments on the Rule and thank you for considering our suggested recommendations and request for clarifications. Again, we commend the Departments for giving plans more time to come into compliance with some of the additional requirements, and we look forward to continuing to work with the Departments on this and other implementation issues related to ACA. If you have any questions, please contact Joel Slackman at 202.626.8614 or Joel.Slackman@bcbsa.com.

Sincerely,

A handwritten signature in black ink that reads "Justine Handelman". The signature is written in a cursive style with a long, sweeping tail on the final letter.

Justine Handelman
Executive Director
Blue Cross Blue Shield Association

MEMORANDUM

**Privileged and Confidential
Attorney Work Product**

September 9, 2010

TO: Joel Slackman

FROM: Jon Breyfogle
Julia Zuckerman

RE: ACA Claims and Appeals Regulation

You asked us to analyze whether courts have been willing to excuse a plan's gross or wholesale mistakes in complying with the claims procedure regulation issued under section 503 of the Employee Retirement Income Security Act ("ERISA") (hereinafter, "ERISA § 503 Regulation"). Additionally, you asked us for our views on the implication of the "strict adherence" standard for group health plans (and group and individual insurance coverage) under the new claims and appeals interim final rule ("IFR") recently issued pursuant to section 2719 of the Public Health Service Act ("PHSA"), as amended by the Patient Protection and Affordable Care Act ("ACA"). 75 Fed. Reg. 43330 (July 23, 2010).

As explained below, under the ERISA § 503 Regulation courts have been unwilling to excuse a plan's mistakes with respect to the processing of claims that prejudice claimants, and have held that a plan's prejudicial errors would result in a "deemed exhaustion" of the plan's appeals process. Under the IFR, which articulates a strict adherence standard, we anticipate that more claims will circumvent a plan's internal appeals process and go straight to the district court for *de novo* review without the benefit of a developed record at the administrative level. The result will be more protracted litigation and more decisions overturning a plan's initial benefit determination.

Our analysis is based upon the laws and related interpretations that are currently in effect, all of which are subject to change. It is possible that a court or federal agency could disagree with our analysis and conclusions.

I. Background

The ERISA § 503 Regulation was adopted in 2001 and articulated minimum requirements for claims procedures pertaining to claims for benefits by participants and beneficiaries under ERISA. These regulations set standards for initial benefit determinations and the appeal of such determinations. The ERISA § 503 Regulation already includes a provision under which a plan administrator's failure to establish and follow minimum procedures would result in a finding that a claimant "shall be deemed to have exhausted the administrative remedies available under the plan and shall be entitled to pursue any available remedies under

section 502(a) of [ERISA] on the basis that the plan has failed to provide a reasonable claims procedure that would yield a decision on the merits of the claim." 29 C.F.R. § 2650.503-1(1).

In a subsequent FAQ interpreting this regulation, the Department of Labor ("DOL") indicated that a plan's mistakes with respect to the processing of a claim or an appeal that do not prejudice a participant will not justify a participant proceeding directly to court without exhausting the plan's claims procedures. DOL *Frequently Asked Questions about the Benefit Claims Procedure Regulation*, FAQ F-2, available at http://www.dol.gov/ebsa/faqs/faq_claims_proc_reg.html. Specifically, the FAQ provided that "not every deviation by a plan from the requirements of the regulation justifies proceeding directly to court . . . [However], deviations not susceptible to meaningful correction through plan procedures, such as the failure to include a description of the plan's review procedures in a notice of an adverse benefit determination, would justify a court determination that the plan failed to provide a reasonable procedure."

ACA establishes a new section 2719 of the PHS Act, which has been incorporated into ERISA and the Internal Revenue Code. See ERISA § 715; Code § 9815. This section requires that group health plans and health insurance coverage (including individual coverage) meet new standards for internal claims and appeals and for independent external review. The section adopts the ERISA § 503 Regulation as the initial standard for internal claims and appeals. Recently, the Departments of Health and Human Services, Labor and Treasury issued the IFR to implement section 2719 of the PHS Act. As required by the statute, the IFR adopts the ERISA § 503 Regulation as a baseline, but it then adds a number of additional provisions relating to internal claims and external review. As relevant here, the IFR provides that:

[I]n the case of an issuer that fails to strictly adhere to all the requirements . . . with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process . . . regardless of whether the plan or issuer asserts that it substantially complied with the requirements . . . or that any error it committed was de minimis. . . . If the claimant chooses remedies under section 502(a) of ERISA, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary.

29 CFR § 2590.715-2719(b)(2)(ii)(F); 75 Fed. Reg. at 43356.

II. Case Law Interpreting the ERISA § 503 Regulation

You asked how courts have interpreted the ERISA § 503 Regulation and whether courts have been willing to excuse incidents of gross or wholesale noncompliance with the ERISA § 503 Regulation. As explained below, the courts generally follow FAQ F-2 in carefully examining compliance with the ERISA § 503 Regulation to determine whether a claimant must exhaust a plan's claims procedure and what standard of review applies to the administrator's decision. Although courts have not mandated strict compliance with every aspect of the ERISA § 503 Regulation, they have adopted standards to ensure substantial compliance with claims procedures so that any mistakes in compliance do not prejudice participants and beneficiaries.

For example, in *Hall v. Baptist Healthcare System, Inc.*, 2007 WL 3119275, at *3-4 (W.D.Ky. Oct. 22, 2007), the court found that the administrator substantially complied with the plan's claims procedures and the ERISA § 503 Regulation even though the administrator's notice letter was technically deficient in failing to explain what additional levels of administrative review were available. The court held that the administrator substantially complied with claims procedure requirements by sending claimant a copy of the plan, which explained the claims appeals process. The court in *Simonia v. Glendale Nissan/Infiniti Disability Plan*, 2010 WL 1896455, at *1-2 (9th Cir. May 12, 2010) found substantial compliance with the Regulation even though the plan did not identify it "Rehabilitation Clinical Case Manager" by name, given that the claimant could not establish any prejudice resulting from this alleged violation.

In contrast, the courts generally find that claimants are deemed to have exhausted their administrative remedies – and can proceed directly to court – where plans failed to issue a decision within the timeframes set out in the ERISA § 503 Regulation. See *White v. Sun Life Assurance Co. of Canada*, 488 F.3d 240, 260 (4th Cir. 2007) (where a plan fails to make a decision within the deadlines articulated in § 2560.503-1(l), "administrative remedies are considered to be exhausted and the claimant is entitled to file suit"); *Kowalski v. Farella, Braun & Martel*, 2007 WL 1342475, at *4 (N.D.Cal. May 7, 2007) ("because defendants failed to issue a decision within 90 days of receipt of plaintiff's appeal, plaintiff is deemed to have exhausted her administrative remedies");

In other instances, where an administrator acted in a timely manner but failed to comply with procedural requirements in a way that caused prejudice to the claimant, courts have similarly refused to excuse the administrator's mistake, and have found that the claimant was deemed to have exhausted his or her administrative remedies. For example, in *Bechtol v. Marsh & McLennan Companies, Inc.*, 2008 WL 238588, at *3-4 (W.D. Wash. Jan. 28, 2008), the administrator adjudicated the claim in a timely manner, but failed to include notice in its claim denial letter of the plan's appeal process and the claimant's right to bring a civil action. The court held that the administrator's mistake "effectively denied [the claimant] 'access to the administrative review process mandated by [ERISA],'" and thus permitted the claimant to proceed with his federal court action without exhausting the plan's administrative remedies. *Id.* at *4, citing 65 Fed. Reg. 70255-56 (Nov. 21, 2000). In *Maynard v. Merrill Lynch & Co., Inc.*, 2008 WL 4790670, at *10-11 (M.D. Fla. 2008), the court held that the claimant would be deemed to have exhausted his administrative remedies where the plan's communications did not inform the claimant of an appeals process and where the plan document did not specify a formal appeal procedure.

Additionally, a finding of deemed exhaustion has resulted in courts applying a *de novo* standard of review to the claimant's benefit claim. See, e.g., *Rasenack v. Tribolet*, 585 F.3d 1311, 1313 (10th Cir. 2009) ("when an administrator violates the statutory deadlines incorporated into the plan, *Firestone* deference no longer applies," and the court reviews the deemed denial *de novo* (citing *Gilbertson v. Allied Signal, Inc.*, 328 F.3d 625, 635 (10th Cir. 2003))). Indeed, several circuits have held that when a claim has been denied by operation of law for failure to abide by the relevant regulatory provisions, such a denial is not entitled to deferential review on the grounds that the administrator has not exercised any discretion. See

Gilbertson, 328 F.3d at 631; *Jebian v. Hewlett Packard Co.*, 349 F.3d 1098, 1103 (9th Cir. 2003); *Kinstler v. Standard Ins. Co.*, 181 F.3d 243, 252 (2d Cir. 1999).

III. Implications of the New Claims Regulation

Clearly, the "strict adherence" standard adopted by the IFR will allow claimants to bring more benefit claim lawsuits under ERISA (as well as under state law with respect to individual insurance) without exhausting a plan's internal claims and appeals process. Unlike the ERISA § 503 Regulation, where courts considered whether a claimant was prejudiced by the plan's processing error, the IFR does not require or permit any analysis of the prejudicial impact of a plan's processing error. Rather, the IFR's strict adherence and deemed exhaustion standard is required regardless of a plan's substantial compliance with its claims and appeals procedure and the IFR or the *de minimis* nature of an error. Such a standard seems to ensure that even minor mistakes that do not prejudice a claimant will trigger "deemed exhaustion" of the administrative process and *de novo* review by the district court. And, the likelihood of non-compliance with at least some aspect of the IFR is particularly high given the myriad of new requirements imposed on plans.

The result will be more litigation and more expensive litigation over benefit claims. As under current law where courts allow claimants to proceed directly to court without exhausting plan remedies, it is likely that the courts will be less willing to defer to the plan's initial decision. Instead, courts may review claims on a *de novo* basis and allow claimants to engage in extensive discovery at the district court level.