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Department of Health and Human Services
Office of Consumer Information
and Insurance Oversight
Attention: OCIIO-9993-IFC

U.S. Department of Labor
Office of Health Plan Standards and Compliance,
Employee Benefits Security Administration
RIN 1210-AB45

Internal Revenue Service
REG-125592-10

Re: The Interim Final Rules, Published July 23, 2010, Relating to the Internal Claims and Appeals and External Review Processes Mandated By Patient Protection and Affordable Care Act ("PPACA") § 1001; Commenting on (New) § 2719 of the Public Health Service Act

Dear Rulemakers:

I offer these comments to the interim final regulations published July 23, 2010 (75 Fed. Reg. 43330, *et seq*.) (the "Interim Rules"), which put into effect new § 2719 of the Public Health Service Act ("PHSA") as recently enacted by PPACA § 1001.

While the Interim Rules automatically take effect for plan years commencing on or after September 23, 2010 for all group health plans and individual policies (other than "grandfathered health plans"[1]), the agencies involved (the Department of Health and Human Services ("DHHS"), the Employee Benefits Security Administration of the U.S. Department of Labor ("EBSA" and "DoL," respectively) and the Internal Revenue

[1] See PPACA § 1251, and the interim final regulations thereto (75 Fed. Reg. 34538; publ. 6.17.10).

Service of the U.S. Treasury Department ("IRS"; jointly with the others, the "Agencies")) have invited public comment, to help identify circumstances where further rulemaking might be warranted.

My comments are intended to bring to your attention some of the more practical issues which need to be addressed – either by modifying the Interim Rules, by providing additional guidance, or (in some instances) by providing some form of transitional or similar relief. Since the Interim Rules consist of parallel rulemaking (i.e., provisions within the Income Tax regulations, the DHHS regulations and the DoL regulations mirror each other), I will refer to the DoL regulations found at 29 C.F.R. § 2590.715-2719(a), *et seq*., to keep things simple. My intent, though, is to comment on each of the parallel provisions.

Perspective

For more than 25 years I have worked with both public sector and private sector employers to facilitate the delivery of health, accident and sickness benefits to current, former and retired employees (and their respective eligible dependents) through employment-based plans. I have found that the methods and means those employers use to provide such benefits varies widely, and is heavily influenced by both the size of the employer's employee population and the regulatory environment within which the employer (and its plan) functions. I also have worked with others in the health care delivery arena, including health insurance issuers and brokers, so I have a reasonable understanding of how the health care delivery system currently operates.

The Tension Between Federal & State Law, And Federal & State Courts

It is axiomatic that an individual's health insurance coverage rights are innately contractual, and that the source of that coverage – whether the coverage is individually purchased (through an individual policy), is acquired through a public sector employer that chose to self-insure, is acquired through a private sector employer that chose to purchase a group policy, or is acquired in some other fashion – dictates whether that individual's contractual coverage rights can be enforced in federal court, in state court, or (in some cases) in either federal or state court. This is true, no matter who seeks to enforce those coverage rights.[2] The source of an individual's health insurance coverage also dictates what substantive and procedural laws apply to controversies that arise over that contractual coverage.

[2] Not surprising, substantially all coverage claims come to be assigned to providers like physician groups and hospital systems, which then attempt to obtain payment from the insurer(s) and plan(s) that provided the coverage. When disputes arise, though, providers generally are left to choose between (a) "stepping into the shoes" of the assignor and enforcing against the applicable insurer and/or plan the rights the assignor held under the policy or plan and relevant law, or (b) returning the assigned claims to the assignor and pursing collection against the assignor. Naturally, exceptions exist (e.g., where the provider has directly contracted with the insurer or plan and can pursue the insurer or plan under a provider agreement based on state law, etc.), but the general rule holds.

It is equally true that so long as the country remains committed to federalism in some form, there will always be uncertainty over exactly where to draw the line between federal law and state law, in part because regulating personal conduct has always been left to the states (and health insurance coverage involves personal choice[3]) and in part because there are some things the federal government has long decided to avoid directly or indirectly regulating, like state and local governments and religious organizations.[4] As the Agencies all know, imposing a uniform set of administrative procedures on a diverse set of procedural and substantive coverage rights, while salutary, was never going to be a simple task.[5] Indeed, determining the source of an individual's health insurance coverage can be tricky. The answer is not always apparent, not even to the individual. Even courts can become confused.

In some cases – including instances where the coverage has been purchased individually, or has not been acquired through an employment relationship that federal law formally recognizes[6] – only state insurance law will apply (including common law doctrines like the "bad faith" doctrine). In those circumstances, an individual's rights are enforceable solely in state court (outside the limited procedural role assigned to federal courts in, e.g., diversity cases). In other cases, though, an individual's rights are enforceable under federal law (such as ERISA) because the coverage was acquired under a group health plan maintained by a private sector employer (or by a

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[3] The states always have maintained primary jurisdiction over matters involving individual behavior, including marriage, guardianship and *ad litem* situations (including minority and indigent determinations). So long as almost 25% of the country's citizens are minors (*See* U.S. Census Bureau, Population Estimates Program, 2009 Population Estimates Data Set, available at http://factfinder.census.gov), and so long as health insurance coverage (and the provision of medical care) involves some level of individual choice, the states will continue to play a central role.

[4] For example, the Kentucky Supreme Court recently decided that a medical expense sharing plan operated by a religious organization (the American Evangelistic Association) constituted health insurance subject to Kentucky's state insurance laws, and not an employer-sponsored benefit plan subject to the Employee Retirement Income Security Act ("ERISA"). *Com. v. Reinhold*, No. 2008-SC-000839-DG, 2010 WL 3374232. (So-called "church plans" maintained by religious organizations can elect out of ERISA and its pre-emptive provisions.)

[5] The Preamble to the Interim Rules signals a desire to remain sensitive to federalism, although in its discussion of Executive Order 13132 (see 75 Fed. Reg. at 43349, Part III.H), it focuses on the rulemaking aspects of PHSA § 2719 and does not seem to tackle the effect the Interim Rules are certain to have on the members of the judiciary (which inevitably will determine the fortunes of any party that comes before one of them).

[6] As the Agencies doubtless are aware, there are private sector situations where ERISA has no application and state law is all that applies, such as "employment-based" plans which cover only partners in a partnership, sole proprietors, or corporate owners, see 29 C.F.R. §§ 2510.3-3(b), (c) (*Plans without employees*) -- or where employees are covered by non-electing "church plans." See Note 4, above.

group of private sector employers acting jointly with a labor organization[7]) or because the individual's employer is the federal government itself (e.g., coverage arising under Tri-Care, or the Federal Employees Health Plan ("FEHP"), etc.). At least with regard to ERISA-related coverage disputes, those rights typically can be enforced in federal court, and in some limited instances in state court, so long as no breach-of-duty claims are brought.[8] In still other cases, where an individual has obtained coverage through a state or local government employer that has elected to self insure, the individual will only be able to sue to enforce those state law-based contract and other rights that the state (or political subdivision) permits the individual to enforce under relevant state and local law, which typically does not include insurance law.[9]

In light of the complex history that has developed to this point, it seems apparent that it will take time for all stakeholders (including the courts) to get fully acclimated to the new regime. Yet, before the end of the current year (2010), federal and state courts will begin to see claims disputes which – according to the Interim Rules – will have to be handled in "strict adherence" to the new procedural rules in order to prevent such claims from simply being re-pled and re-litigated in court, complete with the development of a completely new evidential record (including evidence not previously considered in the administrative process). Doubtless, many courts will struggle to reconcile the precedent developed over the past 30-50 years with the unknown procedural process suddenly sprung upon them. The Interim Rules need to take into account the substantial – and wholly foreseeable – growing pains that all stakeholders will experience (including the courts), and provide the sort of practical guidance needed to simplify, rather than complicate, the process for handling and resolving coverage-related disputes.

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[7] EBSA is well-acquainted with such plans; typically, they are referred to as multiemployer health and welfare plans, or "Taft-Hartley" welfare plans (after the 1947 act which triggered the establishment of most such plans). Compare 29 U.S.C. § 1002(37) (defining multiemployer plans for ERISA purposes) with 29 U.S.C. § 186(c)(5) (identifying the exception, in the Taft-Hartley Act, from the "thing of value" rule for employer contributions made to certain benefit trusts jointly managed by employer and employee representatives) and 29 U.S.C. § 1002(40)(A) (defining "multiple employer welfare arrangements" ("MEWAs") to exclude (among other arrangements) multiemployer plans).

[8] See, e.g., 29 U.S.C. § 1132(e)(1) (ERISA statute defining where federal jurisdiction is exclusive, and where the federal and state courts have concurrent jurisdiction).

[9] Because a sovereign political entity is involved, such rights almost never include "insurance"-type rights (e.g., holding the state or subdivision liable in damages for dealing in "bad faith" if it fails to adjudicate claims properly, requiring the state or subdivision to accept responsibility for coverage ambiguities under the *contra proferentem* doctrine, etc.); rather, such rights invariably are limited to what the state has set forth by statute – typically, under, a statute that selectively waives the state's right to sovereign immunity and limits the amount of damages it must pay. See, *e.g.,* Ohio Revised Code § 2744.01, *et seq.* (waiving sovereign immunity in selected circumstances).

Claims & Appeals: Practical Realities

In General

PHSA § 2719 essentially requires all or substantially all group health plans and health insurance issuers to have and use a reliable "arbitration"-type administrative process (described as an "effective appeals process") to resolve disputes over coverage determinations and related claims. That process requires each group health plan and health insurance issuer to:

1. Have an effective internal claims appeals process for appealing coverage determinations which, at minimum:

   (a) is patterned after EBSA's claims and appeals regulations found at 29 C.F.R. § 2560.503-1,

   (b) effectively communicates to "enrollees" (i) the coverage determinations that have been made, and (ii) how to use that internal claims appeals process and any applicable external review process to challenge adverse determinations, and

   (c) permits "enrollees" to challenge determinations using appropriate due process (e.g., review evidence, provide evidence, etc.) while coverage continues; and

2. Have an external review process which ensures that certain claims (in particular, clinical determinations) are reviewed by an independent review organization ("IRO") that is independently-owned and operated and randomly selected, which either:

   (a) is based on the consumer protection provisions found in the Uniform External Review Model Act promulgated by the National Association of Insurance Commissioners ("NAIC"); or

   (b) is based on a federal standard DHHS will develop, based on the NAIC's Model Act.

Many of the provisions found in the Interim Rules keep faith with these statutory standards and simply amplify what Congress fashioned. However, some provisions could be made much more helpful to everyone involved in the process (including claimants) by simplifying them and making them more precise.[10] Given the stakes, the

[10] For example, the Interim Rules contain a new requirement that if a plan or issuer bases a final adverse benefit determination on a new or additional rationale, the claimant must be provided with the rationale in advance of the final determination to give the claimant a

Interim Rules not only need to be easy for plans, health insurance issuers, plan fiduciaries and claimants to follow, but they also need to be easy for both federal and state courts to use when asked to determine whether the Interim Rules have not been successfully followed.

Simplifying the Interim Rules and making them more precise also will reduce substantially the temptation on anyone's part to game the new rules – which could undermine completely the opportunity to improve what currently is a confusing and inefficient dispute resolution process. The goal of any rational administrative process is to reduce the number of disputes that end up in court, and to make those that do end up in court easier to adjudicate by developing an organized – and presumably, self-contained – administrative record, so the court effectively functions like a court of appeals.[11] The new administrative process Congress has mandated in PHSA § 2719 has to be viewed the same way. In PPACA Congress repeatedly preaches the need to promote efficiency and avoid expensive and duplicative efforts; it cannot be read on the one hand to condemn the defensive practice of medicine, and on the other hand to require (or even encourage) plans and health insurance issuers to engage in the defensive practice of claims management.

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reasonable opportunity to respond. See 29 C.F.R. § 2590.715-2719(b)(2)(ii)(C)(2). It would be easier for plans, issuers and claimants to observe a rule (perhaps, as a safe harbor) which provides that the claimant must be given a specific number of days following a notice of additional reasons for making a particular determination to respond to that determination and/or those reasons, etc. Moving to more precise requirements is particularly essential if the Agencies persist in maintaining a "strict adherence" standard in 29 C.F.R. § 2590.715-2719(b)(2)(ii)(F).

[11] Under most alternative dispute resolution ("ADR") systems, when an independent fact-finder (e.g., an arbitrator, a properly-appointed and empowered fiduciary based on a fully-developed record, etc.) makes an administrative determination, the determination is extremely difficult – and perhaps, close to impossible – to overturn. For example, under the Federal Arbitration Act ("FAA"), an arbitrator's determination is subject to extremely limited, expedited judicial review: the arbitrator's decision can only be overturned if it is the product of corruption, fraud, undue means, misconduct by the fact-finder, material misconduct, or a comparable failing. 9 U.S.C. §§ 10, 11 (2010); Scope of Judicial Review). Also, *Hall Street Assoc. LLC v. Mattel, Inc*., 552 U.S. 576 (2008) (parties cannot by contract expand the scope of judicial review of a dispute resolved by arbitration under the FAA). A claimant would have a powerful incentive to avoid such a limited scope judicial review, which also would permit the claimant to present new evidence to the court. This goes for both arbitrations of the type well-recognized in labor law circles, e.g., *United Steelworkers of America v. Enterprise Wheel & Car Corp.*, 363 U.S. 595 (1960) (courts have narrow scope of review, when bargaining agreement-related interest arbitration decisions and awards are challenged), as well as for fiduciary determinations that come to be made under ERISA. E.g., *Metropolitan Life Ins. Co. v. Glenn*, 554 U.S. 105 (2008).

Suggestions and Recommendations

I appreciate the steps the Agencies already have taken to promptly provide plans, plan sponsors and health insurance issuers with guidance regarding the new claims and appeals requirements, since they are both important and far-reaching. The Interim Rules constitute an important first step. Nonetheless, for as far-reaching and important a provision as PHSA § 2719, additional practical guidance is needed to avoid numerous unintended consequences, to give plans and issuers much-needed time to develop the processes and systems to comply with the Interim Rules, and to prevent (or at least, discourage) individuals from gaming the new federalized system. In an attempt to further those objectives, I offer the following specific suggestions and recommendations:

- Make the Interim Rules An Effective Dispute Resolution Process, Producing Certainty and Finality, Subject to Limited Exceptions. PHSA § 2719 provides relevant stakeholders and the Agencies with a rare opportunity to take pressure off both the federal and state court systems by substituting the sort of alternative dispute resolution system the FAA contemplates, which both the judiciary and the organized bar broadly endorse. While there are isolated provisions in the Interim Rules where this concept begins to be explored,[12] none go far. Instead, there are signs that the Interim Rules could make things worse in at least two respects. First, the Interim Rules encourage claimants to find fault with a plan's (or health insurance issuer's) process and simply by-pass the claims and appeals process and seek an independent, *de novo* adjudication in court; at least as applied to ERISA-based claims, this position undermines 20 years of jurisprudence and ignores the role Congress clearly contemplated that plan fiduciaries would play.[13] Second, the Interim Rules do nothing to address the

[12] The Interim Rules come closest to achieving this objective when describing the effect of a properly-handled external review process. See 29 C.F.R.§ 2590.715-2719(d)(2)(iv) (indicating generally that an external review decision is binding on the plan, the issuer and the claimant (as relevant), but it retreats from that position by obliquely acknowledging that a claimant has "other remedies" without suggesting a review standard comparable to the ones that Congress put in place when crafting the FAA and similar statutes (e.g., the National Labor Relations Act, etc.).

[13] Given the present state of ERISA jurisprudence (notably including *Metropolitan Life Ins. Co. v. Glenn*, 554 U.S. 105 (2008), it seems difficult to conceive that the courts will simply allow claimants to assert a "strict adherence" violation, however insignificant (e.g., a procedural "foot fault," etc.), and flood the courts with demands for, e.g., *de novo* review, new discovery, and consideration of evidence held back from the administrative claims process. That is exactly what the Interim Rules prescribe at 29 C.F.R.§ 2590.715-2719(b)(2)(ii)(F) (last two sentences). The courts may well be more receptive to challenges to the validity of such a position for two reasons: (1) in PPACA § 1001, Congress signaled its general approval of EBSA's existing claims and appeals regulations (see PHSA § 2719(a)(2)(A), sanctioning 29 C.F.R. § 2560.503-1), subject only to a regulatory "update" of the process; and (2) Congress gave no hint in PPACA that it intended to legislate away the more than 20 years of Supreme Court precedent in this area, which dates at least to *Firestone Tire and Rubber Co v. Bruch*, 489 U.S. 101 (1989), or that it intended to make it easy for claimants to supplant the role plan fiduciaries play in the claims and appeals process. Congress usually makes plain when it intends to overturn a single

effect that compliance with the Interim Rules will have, or should have, on state-based litigation (e.g., that adequate compliance with the Interim Rules precludes the assertion of a bad faith claim, or that a failure to comply with the Interim Rules constitutes evidence of bad faith, etc.).

To avoid making the situation worse, the Interim Rules should acknowledge that PHSA § 2719 constitutes a clear signal from Congress that health care coverage arises from a contractual relationship, and that § 2719 is intended to impose a binding dispute resolution process on all parties which requires health care coverage disputes to be subjected to a resolution process every bit as conclusive – and efficient – as that described in the FAA.[14] Doing so would bring the Agencies into line with a long line of legal precedent set down by the U.S. Supreme Court, which for decades has endorsed the use of alternative dispute mechanisms for handling virtually all employment-based contract disputes — even disputes that arose out of virtual contracts of adhesion.[15]

- Recast the "Strict Adherence" Standard – Or at Least The Provision Which Voids the Administrative Fact-Finding Process – to Prevent Claimants From Attempting to Game the System. Under the Interim Rules, claimants are treated as having exhausted the internal claims and appeals process if a plan or issuer fails to "strictly adhere" to all the internal claims and appeals process requirements set forth under the Interim Rules. Perhaps more important, the Interim Rules sanction plans and issuers that fail to strictly adhere to the new

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Supreme Court decision, much less 20+ years of precedent and federal statutes it unambiguously decided to retain. See, e.g., the Older Workers' Benefit Protection Act of 1990 (overturning *Public Employees Retirement System of Ohio v. Betts*, 492 U.S. 158 (1989)) and Lilly Ledbetter Equal Pay Act of 2009 (overturning *Ledbetter v. Goodyear Tire & Rubber Co., Inc.*, 550 U.S. 618 (2007)). Reconsideration by the Agencies of this self-developed standard would avert costly challenges to its validity – and avoid uneven and unpredictable results in the courts.

[14] 9 U.S.C. § 2 (2010), *et seq*.

[15] The U.S. Supreme Court embraced the arbitration of disputes years ago, at least as far back as *Gilmer v. Interstate/Johnson Lane*, 500 U.S. 20 (1991) (trader held required to arbitrate his employment-related discrimination dispute, even though he was required by his employer to sign the arbitration clause as a condition of getting hired), and most convincingly in *Circuit City Stores, Inc. v. Adams*, 532 U.S. 105 (2001) (except for railroad, transportation and certain other workers, the FAA covers all contracts of employment and can be used to compel arbitration of employment-related claims). Even a challenge to the validity of an agreement which contains an arbitration clause is subject to arbitration rather than direct legal review. *Rent-A-Center West, Inc. v. Jackson*, 130 S. Ct. 2772 (2010). It also is axiomatic that coverage provided under or in connection with a bargaining agreement is supposed to be arbitrated; the entire movement started there 50 years ago. See *United Steelworkers of America v. Warrior & Gulf Navigation Co*., 363 U.S. 574 (1960), *United Steelworkers of America v. American Manuf. Co.,* 363 U.S. 564 (1960) and *Steelworkers v. Enterprise Wheel and Car Corp*., 363 U.S. 593 (1960) (the "Steelworkers Trilogy").

procedural rules by allowing claimants to proceed directly to external review or by voiding the entire administrative process and allowing claimants to pursue their claims in court without regard to any "fiduciary" determinations that may have been made and any administrative record that may have been compiled. This standard invites gamesmanship by giving a claimant an incentive to find (or invent) flaws in a plan's or issuer's administrative process so the claimant can race to the courthouse, present his or her claim(s) to a judge, and engage in wide-ranging discovery. Such a rule undermines the central purpose of PHSA § 2719: to provide claimants with adequate due process during the administrative claims (and claims resolution) phase (as opposed to encouraging duplicative process). In the long run, none of the stakeholders to the claims dispute process will benefit from drawing the courts into an ongoing series of disputes which begin with a procedural fight over whether the plan (or issuer) "strict[ly] adhere[d]" to the newly-prescribed administrative process.

The Agencies accordingly should consider re-crafting and recasting the "strict adherence" standard, by (1) substituting a "substantial compliance" standard, and using that as the standard all plans and health insurance issuers must meet, and (2) retaining the "strict adherence" standard but using it as an incentive: plans and health insurance issuers that can demonstrate that they have strictly adhered to the new processes could be permitted to assert it as an affirmative defense in any ensuing litigation, to rebut claims that they have acted in bad faith or breached relevant fiduciary duties, and/or to rebut plaintiff-initiated attempts to recover attorneys' fees under relevant statutes.[16]

Even if the Agencies elect to retain the "strict adherence" standard and confront the inevitable challenges to its validity (see Note 13, above), the Agencies should: (a) put in place a substantial transition period which permits a plan or issuer to "substantially comply" with the Interim Rules (and thereby be treated as satisfying the new standard), (b) temper the provision which purports to invalidate the entire administrative process[17] by simply permitting a claimant to introduce new evidence which a court can take into account as alleged procedural shortcomings when considering the weight to be given any fiduciary or issuer determinations that were made, and (c) put in place an abuse rule, which plans and issuers can invoke to prevent unscrupulous claimants (and their attorneys) from using the standard to pervert the process and drive up health care costs.

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[16] E.g., 29 U.S.C. § 1132(g)(1) (2010) (ERISA's discretionary attorneys' fees statute).

[17] "The claimant is also entitled to pursue any available remedies under section 502(a) of ERISA or under State law, as applicable, on the basis that the plan or issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim. If a claimant chooses to pursue remedies under section 502(a) of ERISA under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary." 29 C.F.R.§ 2590.715-2719(b)(2)(ii)(F).

I offer the following additional thoughts in further support of these recommendations:

- The "strict adherence" standard places too many burdens upon plans and health insurance issuers to be practical. Too often, circumstances beyond a plan's or issuer's control make "strict adherence" to these new procedural and process standards wholly impracticable. For example, plans and issuers frequently cannot obtain from third parties the information needed to responsibly process and resolve certain claims. Similarly, plans and issuers can be expected to encounter difficulty when attempting to accurately identify those claimants who are entitled to receive "culturally and linguistically appropriate" coverage determination notices (further discussed, below). Plans and issuers should not be penalized despite having tried, in good faith, to comply with the new procedural and process rules and despite having substantially complied with them.

- The "substantial compliance" standard has long been recognized by the courts as one that sufficiently protects claimants' rights. Moving to a more rigorous "strict adherence" standard, even as the Interim Rules impose additional procedural burdens on plans and issuers, simply imposes more cost on plans and issuers without providing any additional, demonstrable benefits for claimants.

- Because a failure to satisfy the PHSA § 2719 requirements technically exposes plans, plan sponsors and health insurance issuers (as relevant) to civil sanction under IRC § 4980D (i.e., a tax penalty of $100 per day, subject to certain maximum amounts), the "strict adherence" standard raises the stakes in any subsequent litigation predicated on the alleged inadequacy of the process. This makes it more likely that plans and health insurance issuers will vigorously contest any claimant challenge which is predicated (in part) on the alleged inadequacy of process. That cannot be what Congress envisioned when it crafted a rule designed to make the claims and appeals process more deliberative and due process-oriented – and one presumably designed to resolve coverage disputes at the administrative level.

- As noted above, a "strict adherence" standard will simply invite the unscrupulous to game the system, particularly now that health insurance issuers are required to only spend 15%-20% of every premium dollar on administrative costs under the medical loss ratio ("MLR") rules imposed by PHSA § 2718.[18] An example helps to illustrate this danger. It is entirely possible that some claimants holding small claims, or claims to

[18] PPACA § 1001(5), as amended by PPACA § 10101(f) (enacting PHSA § 2718), and the interim final regulations thereto (publ. at 75 Fed. Reg. 19297).

which a co-payment or deductible has been applied, would begin to employ a "nuisance value" strategy, by constantly appealing adverse benefit determinations and demanding external reviews (even those determinations known to have been properly denied or properly calculated), in the hope that the plan or issuer will simply pay the claimant's personal share rather than incur the steep costs associated with paying outside vendors for a stream of external reviews (external reviews cost upwards of $400 each for standard reviews, much more for expedited reviews).

- Provide Temporary Relief From the IRC § 4980D Penalties. PHSA § 2719 and the Interim Rules not only impose significant new procedural and substantive requirements on plans and health insurance issuers, but they also introduce a potentially expensive civil penalty: a penalty of $100 per day for each violation (subject to certain maximums, and an exception for insured small employer plans[19]). Plans and health insurance issuers will encounter predictable difficulties when converting their current procedures and processes to comply with PHSA §2719 and the Interim Rules, especially given the extremely short time frame. Indeed, for some fiscal year non-grandfathered plans, and for all newly-created plans and coverage, implementation of the first changes is just days away.[20]

  To prevent unfairly burdening those plans and health insurance issuers which are now subject to the civil penalty by virtue of being subject to the Interim Rules, despite their trying in good faith to comply with those new Rules, the IRS should announce a delayed enforcement date for the IRC § 4980D penalties, or at least provide a liberal transition period which takes into account the relative administrative difficulties of complying with the new Interim Rules.

  For example, those plans and health insurance issuers able to demonstrate that they are actively collecting the necessary data to determine whether a given covered population requires notices and other information to be provided in one or more foreign languages should not be subjected to the civil penalty prescribed in IRC § 4980D if unable to accurately identify those populations for the first plan year beginning on or after September 23, 2010 (which could be as

[19] See IRC § 4980D(d) (exempting from the civil penalty any employer of between 2 and 50 employees (taking into account the employer aggregation rules found in IRC §§ 414(b),(c), (m) and (o)) which provides health insurance coverage solely through a contract with a health insurance issuer).

[20] As the Agencies are well aware, the first round of changes take effect as early as September 23, 2010 for new plans and new coverages and non-grandfathered plans (i.e., the new internal appeals rules and the federal external review process), while the second round of changes take effect on the first plan year (or policy year) beginning on or after July 1, 2011 (i.e., the state external review process).

soon as October 1st for some fiscal year plans).[21] Similarly, plans and health insurance issuers which discover that they have an obligation to produce notices and other coverage-related information in a lesser-spoken language (i.e., Swahili or Serbian) should not be subject to the civil penalty so long as they can demonstrate that the translation process is actively being pursued, even though it may take longer to obtain such a translation (as compared with languages where translators with medical language skills are more readily available).[22]

- Clarify Requirements for Providing New or Additional Evidence or Rationale to Claimants. The Interim Rules require a plan or health insurance issuer to provide a claimant, free of charge, with any new or additional evidence or rationale considered, relied upon, or generated by the plan or issuer (or at its direction) in connection with the claim.[23] Such evidence or rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 C.F.R. § 2560.503-1(i), to give the claimant a reasonable opportunity to respond prior to that date. The rule, as written, contains potential traps for the unwary, which (if not clarified) could subvert the entire process – particularly if the Agencies persist in retaining the "strict adherence" standard. Accordingly, I encourage the Agencies to clarify how the rule is supposed to operate in practice.

  My first suggestion would be to specifically define what constitutes "new or additional evidence" and what constitutes a "new or additional rationale," so those terms make sense in context, so the process works on a practical level, and so stakeholders are not free to argue over whether the process is being properly followed. For instance, the phrase "new or additional evidence" implies that the plan or issuer has evidence that the claimant could not reasonably be expected to have (or, to which the claimant likely would not have access); there is no reason why a plan or issuer should have to point out to a

[21] The Preamble to the Interim Rules states that DHHS will publish guidance that issuers may consult to establish the county-level estimates so they can identify whether individuals under their coverage fall within the non-English-speaking thresholds and require non-English notices. This guidance is due "by September 23, 2010." Plans and health insurance issuers should not be held strictly liable for non-compliance with the culturally and linguistically appropriate notice requirements if they are not even able to access the data required to assess their compliance obligations until the time the requirements first become effective. Appropriate transitional relief from all of the relevant penalties (including both the "strict adherence" standard and the civil penalty provisions found in IRC § 4980D) should promptly be adopted.

[22] The Preamble to the Interim Rules suggests the Agencies already understand the difficulty of finding a translator in certain circumstances. See 75 Fed. Reg. 43337 (Part II.e, Note 16) (permitting emergency care determinations to be initially provided in English, to be followed by the translated version).

[23] 29 C.F.R. §§ 2590.715-2719(b)(2)(ii)(C)(1), (2).

claimant evidence the claimant already has (or already knows about), and there likewise is no reason why the claimant should be provided with additional time to respond to such evidence. Similarly, the phrase "new or additional rationale" implies that the plan or issuer has adopted a rationale that either is not intuitive to the claimant or involves a plan or policy provision that is not conspicuous and incontestable (such as a co-pay or deductible provision), or that is based on evidence that is external to the claim or not part of general public knowledge, such as a new study or medical finding that has not been widely published. Accordingly, the "new or additional evidence or rationale" rule should not include the claimant's medical records or other such related information that is within the claimant's control, because the claimant either already has his or her medical records, or they have had the right to access those records. It also should not include any of the plan's or policy's regular terms and conditions, such as a co-pay, annual deductible or similar provision.[24]

My second suggestion, which expands on the comment I offered in Note 109, is for the Interim Rule to provide a reliable time line for handling any "new or additional" information which disrupts the more established process, again so all stakeholders can reliably comply with the new Interim Rules. The Interim Rules impose upon plans and issuers very tight deadlines for making benefit determinations. Indeed, in cases where there are two levels of internal appeals, plans and issuers have just fifteen (15) days to make a determination for pre-service appeals and thirty (30) days to make a determination for post-service appeals. Much of this time is needed to collect relevant provider information, leaving plans and issuers with little time to interpret and apply the information collected to make an actual determination. Requiring plans and issuers to provide the new or additional evidence to claimants "as soon as possible and sufficiently in advance of the date on which the notice of final adverse benefit determination is required" will almost certainly force plans and issuers to miss their final adverse benefit determination deadlines and compromise their ability to meet the "strict adherence" standard discussed above. The logistics are particularly challenging in situations where the documents and information simply cannot be provided electronically, which is the common experience with seniors and with the indigent.[25]

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[24] An example illustrates this point. Assume a plan or issuer initially rejected a claimant's benefit claim *in toto*, on the basis that the services rendered were not 'medically necessary." If, on appeal, that plan's independent fiduciary granted the claim but then applied the plan's annual deductible to it as an offset (i.e., because the claimant had not yet satisfied the plan's annual deductible for the year in question), that "annual deductible" determination cannot reasonably be viewed as "new or additional evidence" or a "new and additional rationale," because the claimant reasonably knew about, and could have (or should have) anticipated that the offset would be taken.

[25] While an overwhelming number of Americans are computer-literate (especially as compared with, e.g., the percentage of compute literate Americans in 2000), many Americans – and especially senior citizens – either do not have access to a computer or do not want access. For

To alleviate the above-described timing pressures (and to prevent plans and issuers from being forced to rush through benefit determinations solely to meet deadlines instead of spending the time necessary to thoroughly and accurately review an appeal and the supplementary information provided by claimants), the Interim Rules should be updated to include a tolling provision such as the one which already exists within the DoL's existing claims procedures. *See* 29 C.F.R. § 2560.503-1(f)(2)(i).

- Limit the Diagnosis and Treatment Codes Required on Adverse Benefit Determination and Final Internal Adverse Benefit Determination Notices. The Interim Rules require plans and issuers to include the diagnosis code in any notice of adverse benefit determination or final internal adverse benefit determination.[26] Just from past professional experience working with health plans, third-party administrators, and health insurance issuers, I know there can be in excess of twenty (20) diagnosis codes for any one claim, if only because medicine often requires practitioners to test for a number of maladies in order to take into account properly the patient symptoms that have presented.[27]

  Because the requirement to include all codes not only could impose a needless burden on plans and issuers but also could confuse the claimant, the Interim Rules should be interpreted to require plans and issuers to report only the *primary* diagnosis code for the ailment in question. This suggestion finds support in the fact that the Interim Rules require plans and issuers to notify a claimant only of "a" diagnosis code, not multiple diagnosis codes. Providing the primary diagnosis code also will help the claimant recall the claim in question and increase the likelihood that the basis for the adverse determination will be clearly understood. Please confirm that this interpretation is correct, and that providing only the primary diagnosis code will fulfill the requirements under the Interim Rules regarding the provision of a diagnosis code.

  The Agencies should also adopt an analysis for the provision of treatment codes on notices of adverse benefit determinations that is the same as is described above for diagnosis codes. It is my interpretation of the Interim Rules that plans and issuers should only have to report treatment codes for

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such individuals, any meaningful exchange of plan-based information or coverage-based information can be both time consuming and expensive.

[26] 29 C.F.R. § 2590.715-2719(b)(2)(ii)(E)(1).

[27] For example, a claimant may go to see a provider for a particular ailment; at that point, the provider may identify a diagnosis code that either generally describes the ailment or that is consistent with the described or manifested symptoms. Upon further examination, however, the provider (or providers) may ascertain that other (more specific) diagnosis codes more closely match the ailment or symptoms. This diagnostic process can repeat itself many times. As such, a single institutional claim can have ten, twenty, or even more diagnostic codes.

treatments and procedures that have been denied or otherwise adversely determined, even if there are other treatment codes that have been approved but that are connected to the same claim as the treatment codes that were adversely determined. Please provide confirmation of this interpretation.

- Confirm Interpretation of "Corresponding Meaning" of Treatment Codes Being Provided. The Interim Rules require notices of adverse benefit determinations and final internal adverse benefit determinations to not only include treatment codes, such as the current procedural terminology ("CPT") codes, but to provide a claimant with their "corresponding meaning[s]."[28] This "corresponding meaning" requirement clearly is intended to describe to a claimant in functional terms what goods and services have been provided, so the claimant understands, in lay terms, exactly what has been done. However, the "corresponding meaning" rule needs to find – and identify – the proper balance between (a) providing a "meaning" so technical that it is incapable of being understood by the claimant, and (b) providing a "meaning" so detailed (but non-technical) that it is capable of being understood not only by the claimant but also by any family member who might have access to the notice(s). An easily-understood notice can function as a double-edged sword.

  Some plans and health insurance issuers already simplify the treatment code descriptions to eliminate some of the detail that might otherwise have been provided to claimants, in order to avoid revealing highly personal information about the treatment(s) the claimant has received – and about the underlying condition(s) which prompted the treatment to be provided – in the belief that the claimant would not want the details revealed to, e.g., family members. Since benefit determinations are not always communicated in a manner (or, under conditions) where the determinations can only be read by the claimant (e.g., determinations mailed to a home address within reach of a spouse or a parent, determinations involving a minor claimant which are provided to a parent or a guardian, etc.) many plans and issuers provide benefit determination notices which rely on treatment descriptors that "desensitize" the treatment information (and thereby preserve the claimant's privacy rights). For example, where a claimant has undergone an abortion procedure, a plan or health insurance issuer might describe the procedure simply as "surgery," to protect the claimant's privacy.

  To allow this process to continue, the Interim Rules should clarify that the term "corresponding meaning" includes the description that a particular plan or issuer reasonably assigns to a particular treatment code, so long as the description being provided contains sufficient information to enable the individual who received the treatment to recognize the claim(s) being made. Much can be gained, and little is lost, when plans and issuers assign a description to a treatment code which effectively communicates to a claimant the details associated with the particular claim that has been made while

[28] 29 C.F.R. § 2590.715-2719(b)(2)(ii)(E)(1).

protecting that claimant's privacy rights, so long as the claimant understands what has been done (and in the case of an adverse determination, why the claim has been determined adversely).

It thus is critically important that plans and health insurance issuers be allowed to retain the discretion to determine what constitutes the "corresponding meaning" for a given treatment code. If plans and issuers are forced to use a certain, medically technical description, they will likely confuse claimants and jeopardize the privacy concerns of claimants. In addition, under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), plans and issuers have an independent obligation to provide only the minimum amount of health information necessary to achieve a particular purpose. So long as plans and health insurance issuers can assign treatment code descriptions that help claimants to identify a particular claim, they are able to satisfy their "minimum necessary" obligations under HIPAA. However, if forced to provide medically technical descriptions, plans, health insurance issuers and similar "covered entities" could run afoul of the "minimum necessary" rule by providing too much sensitive information. To avert this potential conundrum, the Agencies should issue further guidance – preferably, in the form of examples, or perhaps a safe harbor – which confirms that plans and health insurance issuers are entitled to assign simplified treatment code descriptions which serve the twin purposes of (i) helping a claimant easily identify his or her claims, and (ii) protecting the claimant's legitimate right to privacy.

- Make the Internal Appeals Timeframe More Objective and More Predictable. The Interim Rules call for all state external review processes to meet certain minimum consumer protections, including the requirement that a state process must allow at least four months after the receipt of a notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.[29] This "four month" timeframe should be changed to 120 days, to make the deadline more easily ascertainable and capable of being reliably followed, and to ensure that all claimants are given the same number of days to file a request for an external review.[30]

- Clarify the Meaning of "Relevant Notices" and Toll the Response Timeframe in Cases Where Individualized Notices Must Be Translated. PHSA § 2719(a)(1)(B) explicitly requires plans and health insurance issuers to provide a single, general notice to all plan-covered enrollees to generally inform all of their internal and external appeals rights (i.e., "A group health plan and a health

[29] 29 C.F.R. § 2590.715-2719(c)(2)(vi).

[30] It bears noting that the Federal Rules of Civil Procedure ("F.R.C.P."), long used by the judiciary to impose clear deadlines on litigants which can easily be ascertained, cite only "hours" and "days," and not "months," and have a protocol to handle weekends and holidays. *See* F.R.C.P. 6.

insurance issuer . . . shall, at a minimum . . . (B) provide notice to enrollees, in a culturally and linguistically appropriate manner, of available internal and external appeals processes, and the availability of any applicable office of health insurance consumer assistance or ombudsman . . . to assist such enrollees with the appeals processes."). However, the Interim Rules substantially expand that statutory requirement by mandating that group health plans and health insurance issuers provide all of the *individualized* notices required under 29 C.F.R. §§ 2560.503-1(g) (initial benefit determinations) and (1)(j) (reviewed benefit determinations) in a culturally and linguistically appropriate manner.[31]

Since the Interim Rules do not explicitly define "notice" (although a description is provided), and assuming the Agencies are unwilling to revisit the regulatory decision to expand the "culturally and linguistically appropriate" requirement to all of the individualized notices that need to be provided under PHSA § 2719, the Interim Rules need to be clarified to make plain that the new requirement applies to only those individualized notices whose primary purpose is to communicate a decision regarding a particular internal benefit determination. Examples of such notices include: (a) written explanations of benefits, (b) adverse benefit determination notices, and (c) final internal adverse benefit determination notices.

The Interim Rules also should make clear whether independent review organizations ("IROs") are supposed to independently comply with the "culturally and linguistically appropriate" requirement when communicating directly to claimants any decisions they make. While there certainly is some evidence to suggest IROs are not subject to this requirement (i.e., the external review process is not contemplated in the DoL claim and appeals regulations found at 29 C.F.R. § 2560.503-1, and the Interim Rules do not list that requirement as part of the state and federal external review standards[32]), the Interim Rules are not crystal-clear on that point. Also, and of potential equal importance, if the Agencies intend to require IROs to comply with the "culturally and linguistically appropriate" requirement, plans and health insurance issuers need to understand how the ability of an IRO to provide notices in multiple languages fits into the selection process (if at all).

To help ensure that plans and health insurance issuers are in a position to timely comply with the requirements of the statute, and to further the interests of non-English-speaking claimants, the Agencies' guidance accordingly should include a published list of the "relevant notices" that plans and health plan issuers are required to provide in a culturally and linguistically appropriate manner, when the situation dictates.

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[31] 29 C.F.R. § 2590.715-2719(e).

[32] 29 C.F.R. §§ 2590.715-2719(c), (d).

One final point deserves mention in connection with the requirement to provide notices in a "culturally and linguistically appropriate" manner. Some foreign languages are easier to translate – and more widely-spoken – than others. As such, the Interim Rules could benefit from having a brief tolling period which provides plan administrators and health plan issuers the time needed to have individualized notices translated into the appropriate language(s). It is comparatively easy for plans and health insurance issuers to maintain boilerplate language, in a variety of foreign languages, which can be used to respond to more generic claims or which can be used in a number of different contexts when communicating with claimants (e.g., treatment code descriptions, appeals process descriptions, etc.). However, it will be difficult for plans and health insurance issuers to satisfy the response deadlines when they have to locate and properly engage interpreters that have the relevant medical language skills and linguistic skills needed to translate some of the more individualized medical and other information which will now be required to be included in certain of the notices.[33] Accordingly, the Agencies should consider allowing plans and issuers to invoke a fifteen (15)-day tolling period, to enable them to prepare appropriate (and appropriately precise) translated notices. Alternatively, plans and issuers could be permitted to provide a notice in English, which could then be followed in due course by the translation – an approach the Agencies already seem to have embraced.[34]

- Provide Guidance on Whether Plans, Issuers Can Charge a Fee to Provide "Relevant Notices" in Non-English Languages. The Interim Rules clearly seek to expand a claimant's understanding of his or her procedural and substantive rights, first by requiring that the claimant be provided with considerable detail regarding the decision and the relevant procedural rights, communicated in a manner that the claimant can understand,[35] and second by requiring that even the individualized notices must be provided in a culturally and linguistically appropriate manner (as noted immediately above). Producing translated, individualized notices could prove to be quite expensive for plans and health insurance issuers, particularly for those scheduled to become directly or indirectly subject to the sharp restrictions being placed on the percentage of premium health insurance issuers can spend on administrative expenses and related items under PHSA § 2718 (the MLR rules). As such, guidance should

[33] Naturally, handling such individualized and sensitive information will require the interpreters to comply with all of the relevant HIPAA and HITECH privacy provisions (see my Treatment Code comment, above) as "business associates" of the relevant "covered entit(ies).

[34] The Agencies already have indicated that in emergency care situations, a plan or issuer will be able to first issue a notice in English, and then subsequently issue the translation. See Note 22 (above).

[35] 29 C.F.R. §§ 2590.715-2719(b)(2)(ii)(E) (contents of the Notice) and (e) (in certain circumstances, requiring Notices to be provided in a culturally and linguistically appropriate manner).

be provided, either in conjunction with the Interim Rules or in conjunction with the rules and regulations being promulgated under PHSA § 2718, or generally, indicating whether health insurance issuers, and plans, can charge plan sponsors a fee for providing such translations.

- Clarify the Effective Date For Complying With the Simultaneous Internal/External Review Rules. The Interim Rules clearly require that in certain circumstances (in general, emergencies, life-threatening situations and situations where denial of care would have potentially permanent consequences), a claimant must be permitted to apply for an expedited external review while simultaneously seeking an expedited internal review.[36]

  The Interim Rules make clear that the new standards relating to the handling of internal appeals are effective for plan years beginning on or after September 23, 2010, for all but grandfathered plans.[37] The effective date for handling external reviews is less clear; depending on circumstances, that requirement could be read to only take effect for plan years commencing on or after July 1, 2011.[38] That seeming split in effective dates has been a source of confusion, particularly for claims which need to be subjected simultaneously to both an internal review and an external review. While it is possible to infer from the presence of the transition period found with the state-based external review rule that the external review requirement takes effect at the same time as the internal review requirement,[39] the general statement (found in 29 C.F.R. § 2590.715-2719(c)(1)) clouds the issue. Accordingly, it would be very helpful for the Agencies to confirm that the external review process requirement generally takes effect for plan years commencing on or after September 23, 2010.

  A related question relates to the handling of certain external reviews as and when the transition period (described in 29 C.F.R. §§ 2590.715-2719(c)(3)) ends. Clause (ii) of that transition rule indicates that the ability of a plan (or an issuer) to use the state external review process generally ends as of the first plan year commencing on or after July 1, 2011, for any final internal adverse

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[36] 29 C.F.R. §§ 2590.715-2719(c)(2)(iii), (xiii) (state process); and 29 C.F.R. §§ 2590.715-2719(d)(2)(ii)(A) (federal process).

[37] 29 C.F.R. §§ 2590.715-2719(g) (general effective date).

[38] The result may well depend on the plan's regulatory posture (e.g., whether ERISA applies, whether relevant state law has an external review process, etc.). See 29 C.F.R. §§ 2590.715-2719(c)(1).

[39] 29 C.F.R. §§ 2590.715-2719(c)(3)(i) provides that there are at least some plans, with plan years which commence on or after September 23, 2010 but prior to July 1, 2011, which will be entitled to use an applicable state external review process for the initial plan year in lieu of complying with the federal standard, but only if there is an applicable state external review process. (If there is no applicable state standard, the federal standard is supposed to apply.)

benefit determination, or adverse benefit determination (in the case of a simultaneous internal appeal and external review) which is "provided" after the prior plan year ends. The term "provided" is a source of confusion; it suggests that some external reviews commenced prior to the close of the transition plan year will have to be redone, simply because they aren't completed (and thus, "provided") prior to the date the federal external review process takes effect with respect to the plan and/or the issuer. Accordingly, it also would be helpful to have the Agencies clarify exactly how the "transition period" effective date found in 29 C.F.R. §§ 2590.715-2719(c)(3))(ii) is supposed to function when that period ends – preferably, by providing a concrete example.

- Clarify Operation of the Interim Rules' Relevant Effective Dates For Incurred But Not Reported ("IBNR") Claims, Pending Claims, And Plans Losing "Grandfathered Plan" Status. One final comment is warranted, pertaining to effective dates.

  The September 23, 2010 effective date for the changes wrought by PPACA §1001 is now imminent. Accordingly, plans and health insurance issuers (and their advisors) are now beginning to cope with the many practical issues associated with subjecting existing plans to all the new rules (including, but not limited to, the claims and appeals procedures mandated by PHSA §2719 for all plans and coverages that do not have "grandfathered plan" protection). One of the most vexing problems now being encountered is the lack of practical "effective date" guidance, so plans and health insurance issuers can determine *which* benefits, and what claims, are subject to the new PPACA mandates – including the Interim Rules.

  This need for practical guidance is acute, due to the nature of group health plans and health insurance coverage. Few plans are more dynamic than a group health plan, and few forms of insurance are more dynamic than group health insurance. Indeed, many claims arise before the plan or the issuer (as applicable) become aware of their existence, and can take several months to be presented for an appropriate determination. That is why there is even a term which describes such claims: "incurred but not reported" ("IBNR") claims. Still other claims, even though presented to a plan or issuer for adjudication, take months to assess, adjudicate and (hopefully) resolve under whatever claims and appeals process presently is in place.[40]

  The Interim Rules generally ignore the presence of these so-called "pipeline" claims; the Rules specify only (a) that the new requirements apply for plan years beginning on or after September 23, 2010, and mention that

[40] Under existing rules, that process can even consist of a grievance and arbitration process, established and operated in accordance with a collective bargaining agreement. See 29 C.F.R. §2560.503-1(b)(6) (specifying how grievance and arbitration procedures can satisfy some or all of the current DoL claims and appeals rules, depending on the scope of the collective bargaining agreement involved).

grandfathered health plans are not subject to the new rules,[41] and (b) that plans and health insurance issuers which become subject to the Interim Rules prior to July 1, 2011, will be able to use an applicable state external review process rather than the new federal external review process, until the first plan year commencing on or after that 2011 date.[42] \

While many practitioners infer from the Interim Rules (and the absence of any special provisions) that the new procedures must be followed when handling any (and every) claim determination submitted, or appealed, after the prescribed effective date (i.e., the first plan year commencing on or after September 23, 2010, or the day an existing plan or coverage loses its "grandfathered health plan" status), more practical guidance is needed so plans, plan fiduciaries, service providers, and health insurance issuers all clearly understand what to do with previously-incurred claims that either have not yet been submitted, or that have been submitted but have not been completely determined or resolved through the existing administrative process.[43]

The Agencies obviously are sensitive to this problem: last month, they issued Technical Release No. 2010-1 (publ. 8.23.10), to help self-insured plans cope with the new federal external review process found at 29 C.F.R. §2590.715-2719(d), et seq., and just yesterday announced in Technical Release No. 2010-2 (publ. 9.20.10) that they would take a "no-enforcement" position until July 1, 2011 with regard to certain of the new requirements outlined in the Interim Rules, so long as the plans and issuers involved are working in good faith to comply with those requirements.[44] The Agencies' efforts at providing further transitional relief are appreciated, but do not prevent private litigants from turning to the courts. Those efforts also do not help plans and issuers

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[41] 29 C.F.R. §2590.715-2719(g).

[42] 29 C.F.R. §2590.715-2719(c)(3).

[43] It already will be difficult for plan sponsors, plan fiduciaries and health insurance issuers to accurately administer a single new claims and appeals process while handling both pre-PPACA benefit plan claims (i.e., those arising under the plan' terms prior to taking into account any of the PPACA-mandated changes) and post-PPACA benefit plan claims (i.e., those which take into account all of the recent mandates, to the extent not rendered inapplicable due to the presence of "grandfather" relief). Requiring those parties to discern which claims should be subjected to which plan provisions and procedures simply asks too much of them.

[44] Technical Release No. 2010-2 specifically provides relief from (1) the time frame for making urgent care claims decisions, (2) the obligation to provide determination notices in a culturally and linguistically appropriate manner, (3) the obligation to provide broader content and specificity in determination notices, and (4) the obligation to strictly adhere to all of the Interim Rules' new requirements.

determine with some degree of certainty how and when the new rules are supposed to apply to existing claims – regardless whether such claims have been made, or are presently being considered by, e.g., a plan or one of its fiduciaries, or by an issuer, or by an existing IRO pursuant to an existing state law process.

Accordingly, the Agencies could head off a host of problems, and doubtless a number of court cases, simply by publishing guidelines for (a) handling claims that have been incurred prior to the effective date specified in 29 C.F.R. §2590.715-2719(g) (including claims which either have not yet been reported or which have not yet completed the plan's or issuer's then-current claims and appeals process), and (b) handling claims under plans and coverages which, at some future point, lose their "grandfathered health plan" status.

Conclusion

The Interim Rules provide important and helpful guidance regarding the new claims and appeals provisions found in PHSA § 2719. But they need to provide additional clarity in several key areas. They need to also serve the broader objective of providing a process which makes it easier – and not more difficult – to resolve coverage and coverage-related disputes, or more expensive or duplicative. Accordingly, I hope the Agencies will take into account the above concerns, suggestions and recommendations, and provide substantial additional guidance.

I appreciate the opportunity to provide these comments; in the event any of the Agencies involved have any questions regarding them, I invite those inquires and would be pleased to respond.

Respectfully submitted,

John J. McGowan, Jr.

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