Bloomberg BNA

Pension & Benefits Daily ™

View From Groom: DOL and HHS Enforcement Activities Targeting Health Plans and Insurers

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Now that the Patient Protection and Affordable Care Act's (the ''ACA'') ''insurance market reforms'' and the changes required by the Mental Health Parity and Addiction Equity Act (''MHPAEA'') have gone fully into effect, many health plan sponsors and insurers are now focusing on compliance and how these laws will be enforced – and more specifically, the audit and investigation risks they face from regulators. Frequently, the issue is phrased as follows: *who* can investigate, and *what* is the investigator looking for? Unfortunately, the answer to both of these seemingly straight-forward questions is complex, given that the ACA and MHPAEA's enforcement scheme splits regulatory authority between state governments and the federal government—and even federal enforcement is split among three different agencies, depending on the type of health plan at issue. This tangled enforcement scheme runs the risk of overlapping enforcement actions that could impose significant and unnecessary compliance costs on plan sponsors and insurers.

This article provides a high-level overview of how ACA and MHPAEA enforcement authority is allocated between the states and the federal government, and how (and when) three federal agencies – the Department of Health and Human Services (''HHS''), the Department of Labor (''DOL'') and the Internal Revenue Service (the ''IRS'') – may enforce the ACA and MHPAEA. We then discuss current enforcement activities by HHS and DOL against insurers and plan sponsors. And finally, the article offers suggestions on how insurers and plan sponsors can best prepare for ACA and MHPAEA audits.

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I. The ACA's Insurance Market Reforms

The ACA requires that insurers and sponsors of group health plans modify their coverage to comply with various mandates set forth in Subtitle A (relating to individual and group market reforms) and Subtitle C of Title I of the ACA (relating to health insurance market reforms) (collectively, the ''insurance market reforms''). Specifically, the ACA amended title 27 of the Public Health Service Act (''PHSA'') directly, and then the insurance market reforms were incorporated by reference into section 715 of the Employee Retirement Income Security Act (''ERISA'') and section 9815 of the Internal Revenue Code (the ''Code'').

Some of the ACA insurance market reforms apply with equal force to health insurance companies as well

as group health plans—such as the requirements to extend coverage to adult children until the age of 26,[1] and the elimination of annual and lifetime dollar limits and pre-existing condition exclusions.[2] Some ACA market reforms, however, apply solely to health insurance companies, including medical loss ratio rules (which require insurers to spend a specified amount on the reimbursement of health care claims or quality improvement activities),[3] the offering of the essential health benefits package (a statutorily specified package of health benefits that insurers in the individual and small group markets must cover),[4] guaranteeing the issuance or renewal of health insurance coverage (without regard to medical underwriting or preexisting conditions),[5] and community rating rules (which limit the factors that insurers may consider when setting premium rates).[6] And even the application of these rules may differ, depending on whether the group health plan or insurance coverage is considered a ''grandfathered'' plan that is exempt from some – but not all – of the ACA's insurance market reforms.[7] A list of the insurance market reforms and their statutory effective dates is summarized as follows:

ACA Insurance Market Reforms Applicable to Non-Grandfathered Plans	ACA Insurance Market Reforms Applicable to Grandfathered Plans
2011 Plan Year (Assuming a 1/1 start date)	**2011 Plan Year**
■ No annual limits on essential benefits. Applies to individual and group health insurance coverage, and self-funded plans.	■ No annual limits on essential benefits. Applies to group health insurance coverage and self-funded plans.
■ No lifetime limits on essential benefits. Applies to individual and group health insurance coverage, and self-funded plans.	■ No lifetime limits on essential benefits. Applies to individual and group health insurance coverage, and self-funded plans.
■ No rescissions (except for fraud or misrepresentation). Applies to individual and group health insurance coverage, and self-funded plans.	■ No rescissions (except for fraud or misrepresentation). Applies to individual and group health insurance coverage, and self-funded plans.
■ Must offer coverage to adult children of insured up to age 26. Applies to individual and group health insurance coverage, and self-funded plans.	■ Must offer coverage to adult children of insured up to age 26. Applies to individual and group health insurance coverage, and self-funded plans.
■ Must provide rebates if plan does not meet required medical loss ratio. Applies to individual and group health insurance coverage.	■ Must provide rebates if plan does not meet required medical loss ratio. Applies to individual and group health insurance coverage.
■ No preexisting condition exclusions for enrollees under 19 years old. Applies to individual and group health insurance coverage, and self-funded plans.	■ No preexisting condition exclusions for enrollees under 19 years old. Applies to group health insurance coverage and self-funded plans.
■ Must provide coverage for immunization or preventive care with no cost-sharing. Applies to individual and group health insurance coverage, and self-funded plans.	
■ No discrimination in favor of highly compensated individuals. Applies to group health insurance coverage.	
■ Must allow individuals to choose pediatrician for child's primary care physician. Applies to individual and group health insurance coverage, and self-funded plans.	
■ Must allow females to choose gynecologist or obstetrician without referral. Applies to individual and group health insurance coverage, and self-funded plans.	
■ Must allow emergency services without preauthorization and treated as in-network. Applies to individual and group health insurance coverage, and self-funded plans.	
■ Must provide internal appeals and external review process. Applies to individual and group health insurance coverage, and self-funded plans.	
March 2012	**March 2012**
■ Must create summary documents using HHS uniform definitions. Applies to individual and group health insurance coverage, and self-funded plans.	■ Must create summary documents using HHS uniform definitions. Applies to individual and group health insurance coverage, and self-funded plans.
Plan Year 2014	**Plan Year 2014**
■ No annual limits on es-	■ No annual limits on es-

[1] PHSA section 2714.
[2] PHSA sections 2711 and 2704.
[3] PHSA section 2718.
[4] PHSA section 2707.
[5] PHSA sections 2702 and 2703.
[6] PHSA section 2701(a).
[7] A grandfathered plan is a group health plan or insurance coverage that was in effect on the date of the ACA's enactment (March 23, 2010) with benefits and cost-sharing that have remained essentially unchanged since that date. HHS, DOL, and the IRS have published regulations detailing specific changes to either benefits or cost-sharing that will trigger loss of grandfather status. *See* 75 Fed. Reg. 34538 (June 17, 2010). The specific changes that will trigger loss of grandfather status are codified at 26 CFR § 54.9815-1251T(g), 29 CFR § 2590.715-1251(g), and 45 CFR § 147.140(g). Once grandfather status is lost, the plan or coverage at issue must comply with all applicable ACA market reforms.

sential benefits (where HHS previously has allowed restricted annual limits). Applies to individual and group health insurance coverage, and self-funded plans.	sential benefits (where HHS previously has allowed restricted annual limits. Applies to group health insurance coverage, and self-funded plans.
■ No pre-existing condition exclusions on any enrollees. Applies to individual and group health insurance coverage, and self-funded plans.	■ No pre-existing condition exclusions on any enrollees. Applies to group health insurance coverage, and self-funded plans.
■ Waiting periods limited to 90 days. Applies to group health insurance coverage and self-funded plans.	■ Waiting periods limited to 90 days. Applies to group health insurance coverage and self-funded plans.
■ No discrimination against individual participating in a clinical trial and must cover routine costs for items or services furnished in connection with a clinical trial. Applies to individual and group health insurance coverage, and self-funded plans.	
■ Must follow rating limitations (rating based on: tobacco use 1.5:1, age 3:1, rating area, and coverage for individual versus family). Applies to individual and small group health insurance coverage only, unless large group coverage is offered through an exchange.	
■ Guaranteed issue. Applies to individual and group health insurance coverage.	
■ Guaranteed renewability. Applies to individual and group health insurance coverage.	
■ No discrimination based on health status. Applies to individual and group health insurance coverage, and self-funded plans.	
■ No discrimination on health care providers acting within the scope of their license. Applies to individual and group health insurance coverage, and self-funded plans.	
■ Must cover the essential health benefits package. Applies to individual and small group health insurance coverage.	
■ Must follow cost sharing limits. Applies to individual and group health insurance coverage, and self-funded plans.	
No Effective Date Yet	
■ Transparency of coverage and quality of care reporting.	

II. MHPAEA Changes Regarding Mental Health and Substance Use Benefits

MHPAEA amended the PHSA, ERISA and the Code to prohibit group health plans that provide mental health/substance use benefits from applying ''financial requirements'' or ''treatment limits'' to those benefits that are more restrictive than the ''predominant'' financial requirements or treatment limits that apply to ''substantially all'' medical/surgical benefits. MHPAEA defines ''financial requirements'' to include deductibles, copayments, coinsurance and out-of-pocket expenses; ''treatment limitations'' to include limits on the frequency of visits, number of visits, days of coverage, or other similar limits on the scope or duration of treatment; and the term ''predominant'' to mean the most common or frequent of such type of limit or requirement.[8]

In 2010, HHS, DOL and the IRS jointly published an interim final regulation (the ''IFR'') implementing MHPAEA.[9] The IFR is applicable to group health plans and group health insurance issuers for plan years beginning on or after July 1, 2010.[10] The IFR is in effect until the final MHPAEA regulations discussed below (the ''Final Rule'') become applicable — which is the plan year beginning on or after July 1, 2014 (*i.e.*, January 1, 2015 for calendar year plans).

The IFR provides that the MHPAEA's parity requirement applies to both quantitative and non-quantitative treatment limitations (''NQTL''). An NQTL is a limitation that restricts coverage under the plan which is not expressed numerically. This requirement extends to medical management standards limiting benefits based on, for example, medical necessity or an exclusion for experimental/investigational treatments; prescription drug formulary designs; and standards for determining provider admission in a network, including reimbursement rates.[11] The IFR requires that any processes, strategies, evidentiary standards or other factors used in applying ''non-quantitative treatment limits'' to mental health/substance use benefits be comparable to – and applied no more stringently than – those applicable to medical/surgical benefits in the same ''classification.'' The classifications for which parity is required as to both financial requirements and treatment limitations are as follows:

- inpatient, in-network;
- inpatient, out-of-network;
- outpatient, in-network;
- outpatient, out-of-network;
- emergency care; and

[8] ERISA section 715(a)(3)(A).
[9] 75 Fed. Reg. 5410 (February 2, 2010) (codified at 26 CFR Part 54, 29 CFR Part 2590, 45 CFR Part 146).
[10] *Id.* at 5410.
[11] 29 CFR § 2590.712(c)(4)

■ prescription drugs. [12]

The NQTL requirement is a key issue for virtually all plans and employers. Probably its most important impact has been the high level of scrutiny now applied to prior authorization requirements for outpatient mental health/substance use services, particularly if no (or very few) similar requirements are applied to medical/surgical outpatient services.

The Final Rule, which takes effect for plan years beginning on or after July 1, 2014, builds on the foundation established by the IFR with some changes that codify guidance issued through frequently asked questions released after the IFR and expand the reach of the MHPAEA's application, including:

■ Addition of new sub-classifications for the six categories of benefits;

■ Inclusion of new NQTLs that plans and issuers must consider in their parity analysis;

■ Inclusion of new disclosure requirements for documents evidencing the parity analysis;

■ Clarification that plans and issuers do not have to test plan designs that have not changed for parity each year;

■ Clarification that a plan that provides coverage for a mental health/substance use condition solely to comply with the ACA's preventive services mandate does not have to provide the full range of benefits for the mental health/substance use disorder under MHPAEA;

■ Clarification that employee assistance plans (''EAPs'') that do not provide significant medical benefits may be treated as ''excepted benefits'' and will not be subject to the MHPAEA or the Final Rule; and

■ Clarification of the intersection of the MHPAEA parity requirements and state law mandates.

III. The ACA and MHPAEA's Complex Enforcement Scheme

The discussion above provides just a high-level summary of the ACA insurance market reforms and the MHPAEA rules, but even this summary makes clear that compliance with the myriad of complex new rules will be challenging for even the most sophisticated plan sponsors and insurers. Adding to the complexity is the rather Byzantine means by which the ACA market reforms and MHPAEA are enforced by public agencies.

Specifically, the enforcement mechanism for both the ACA and MHPEAEA is based on the enforcement provisions of the Health Insurance Portability and Accountability Act (''HIPAA'').[13] HIPAA created a detailed framework that allocates enforcement authority to states and HHS with respect to health insurance issuers, and then further allocates enforcement authority among HHS, DOL, and the IRS with respect to varying types of group health plans.[14] Specifically, enforcement authority under HIPAA is divided as follows:

A. States Are Primary Enforcers Against Health Insurers, With HHS Having a 'Fallback' Role

Under the PHSA, HHS has enforcement authority over health insurance issuers and nonfederal governmental plans. HIPAA contemplates, however, that *states* will have primary enforcement authority over health insurers,[15] with states having their traditional power to conduct market conduct exams, to levy fines for non-compliance with state insurance laws, and/or to withhold or withdraw approval of products that do not conform to applicable legal requirements. It is only *if* a state notifies HHS that it does not have authority to enforce, or HHS determines that a state has failed to ''substantially enforce a provision''—that HHS is then authorized to enforce all or part of HIPAA, MHPAEA, or the ACA's market reforms against health insurance issuers operating in that state,[16] via the imposition of civil penalties of up to $100 per day, per individual with respect to whom a failure to comply has occurred, which are subject to administrative and judicial review.[17] HHS may only impose these penalties on health insurance issuers and nonfederal government plans; HHS is not authorized to impose penalties on ERISA-covered group health plans.[18]

In enacting the ACA, Congress also provided HHS with the authority to establish criteria for the certification of qualified health plans (''QHPs'') that may be offered on state-based Exchanges or the federally-facilitated Exchanges or Marketplaces established by HHS (the ''FFM'').[19] HHS has issued regulations relating to QHP certification standards, and such regulations provide that HHS may, among other things, assess penalties against issuers that fail to satisfy applicable QHP certification standards.[20]

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[12] 75 Fed. Reg. at 5433; 29 CFR § 2590.712(c)(2)(ii).

[13] *See* Preamble to the HHS Final Premium Rate Review Regulation, 78 Fed. Reg. 13406, 13419 (February 27, 2013) (''[T]he HIPAA enforcement standard, as originally codified in [PHSA] section 2722 and redesignated as section 2723 by the Affordable Care Act, applies to the market reform provisions of the [PHSA] created by the Affordable Care Act.'').

[14] The agencies have entered into a formal memorandum of understanding (''MOU'') that details the agencies' agreement to coordinate their respective HIPAA regulatory, interpretive, and enforcement strategies. *See* 64 FR 70164 (December 15, 1999). Pursuant to this MOU, the agencies have issued joint regulations interpreting HIPAA and the ACA's requirements as applied to health insurers and group health plans. The agencies also share enforcement data under the MOU, and specifically agree to notify each other in writing prior to the commencement of any administrative or judicial proceeding relating to enforcement.

[15] PHSA section 2723(a)(1) (states ''may require that health insurance issuers . . . meet the requirements of this part'').

[16] PHSA section 2723(a)(2). *See also* 45 CFR section 150.201, which provides that ''each State enforces HIPAA requirements with respect to health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State.'' HHS is permitted to enforce a HIPAA provision against a health insurance issuer in a state only if a state notifies HHS it is not enforcing, or HHS determines – after notice to the state and an opportunity for the state to correct any alleged deficiencies – that the state either does not have the authority to enforce such provisions, or fails to substantially enforce such provisions. *See* 45 CFR sections 150.207-219.

[17] PHSA section 2723(b)(2).

[18] PHSA section 2723(b)(2)(A).

[19] ACA section 1311(c).

[20] 45 CFR section 156.805(a) (listing specific grounds for imposing civil monetary penalties).

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B. DOL Enforces Against ERISA-Covered Plans—But Not Insurers

ERISA, as amended by HIPAA, provides that group health plans and health insurance issuers must comply with HIPAA's preexisting condition and portability provisions.[21] ERISA provides a combined scheme of public and private enforcement by the DOL and plan participants. Specifically, plan participants and beneficiaries may bring suit to recover benefits due under the terms of a plan.[22] And participants, beneficiaries, plan fiduciaries, and the DOL may sue to enforce the requirements of ERISA Title I (which includes Part 7, codifying the HIPAA, MHPAEA and ACA rules) or to enforce the terms of the plan.[23] Importantly, however, DOL generally does not have the authority to assess civil monetary penalties against plans (or their fiduciaries) for noncompliance with the HIPAA reforms, or those enacted by MHPAEA or the ACA.

At the time of enacting HIPAA, however, Congress also added new section 502(b) to ERISA. Section 502(b)(3) provides that with an exception not relevant here (relating to the assessment of civil penalties for failing to provide certain disclosures), the DOL is ''is not authorized to enforce under this part any requirement of [ERISA] part 7 against a health insurance issuer offering health insurance coverage in connection with a group health plan[.]''[24] In other words, DOL may not enforce any provisions of ERISA Part 7—which includes MHPAEA and the ACA market reforms—against health insurers.

C. The IRS Enforces Against ERISA-Covered Plans and Church Plans

The HIPAA enforcement framework also provides the IRS with enforcement authority over group health plans, including church plans, and their sponsors. The IRS exercises this enforcement through the imposition of an excise tax of $100 per day, per individual affected by such noncompliance.[25] Group health plans are required to self-report violations of HIPAA's rules (as well as violations of the ACA's market reforms) on the IRS Form 8928, and to pay the resulting penalties.

IV. Recent Enforcement Activities by HHS and DOL Targeting Health Plans

Now that MHPAEA's Final Rule has been issued and the ACA's insurance market reforms are fully in effect, it is not surprising that regulators are auditing plans and insurers for compliance with the new rules. What is surprising, however, is just how wide-ranging these audits by HHS and DOL are, and how much documentation and verification is required to establish compliance with MHPAEA and the ACA's insurance market reforms.

A. MHPAEA Audits By HHS and DOL

In the past year, there has been a discernable uptick in MHPAEA audits conducted by HHS and states (targeting health insurers) and DOL (targeting both group health plans and insurers). HHS audits frequently examine the insurer's compliance with MHPAEA across the insurer's entire book of insured business, and can thus be enormously time consuming and intensive given all the variations that may exist in product and plan designs. DOL audits are usually more targeted in terms of the number of plans at issue, usually focusing on just one or a relatively small number of plans that an insurer may be administering. In either case, though, the information sought by HHS and DOL is voluminous, focusing on, among other things:

- Comparison of financial benefits for medical/surgical coverage versus mental health/substance use coverage;
- Parity of participant cost-sharing for medical/surgical benefits and mental health/substance use benefits;
- Comparison of treatment limits for medical/surgical and mental health/substance use benefits;
- Comparison of NQTLs for medical/surgical benefits and mental health/substance use benefits, such as the stringency with which prior authorization or utilization review may be applied to mental health/substance use benefits;
- Criteria used to determine and define medical necessity for mental health/substance use benefits, as compared to criteria for medical/surgical benefits;
- Placement of mental health/substance use drugs on a prescription drug formulary and how it compares to drugs to treat medical/surgical conditions;
- Standards for classifying mental health/substance use disorder services and medical/surgical services as outpatient, inpatient, or emergent or urgent care services, as well as any sub-classifications for office visits or multi-tiered networks;
- Coverage of residential treatment facilities for mental health/substance use services, as compared to coverage of skilled nursing facilities for medical/surgical benefits;
- A list of all mental health/substance use benefits that are either covered by the plan at issue or excluded, as well as a comparable list for all covered or excluded medical/surgical benefits;
- Information on how plans and insurers process claims and appeals involving mental health/substance use benefits;
- Disclosure of denied or partially denied mental health/substance use claims, and how they compare to denied medical/surgical claims;
- All external review decisions relating to mental health/substance use claims
- Internal analyses prepared by a plan or insurer (or a consultant), testing the plan or product's medical/surgical benefits for parity against mental health/substance use benefits.

B. ACA Audits by HHS and DOL

HHS and DOL have also been quite active in launching investigations of insurers and plans to assess com-

[21] ERISA sections 701-702.
[22] ERISA section 502(a)(1)(B).
[23] ERISA sections 502(a)(3) and (a)(5).
[24] empty footnote
[25] Code section 4980D(b)(1).

pliance with the ACA's insurance market reforms. As discussed above, the HIPAA enforcement framework contemplates that states will be the primary enforcers of the ACA's market reforms as applied to insurance companies, and to be sure, many states are enforcing these reforms through their product review and approval processes.[26] But in five states – Alabama, Missouri, Oklahoma, Texas and Wyoming – HHS has assumed the sole enforcement role.[27] Moreover, we understand that in the context of reviewing compliance with federal Exchange certification standards, HHS may have sought information about some QHP issuers' compliance with the ACA's insurance market reforms—even in states where insurance regulators are themselves enforcing the reforms.[28]

DOL has also announced a comprehensive national enforcement initiative, known as the Health Benefits Security Project (''HBSP''), which involves a broad range of health care investigations—including examinations of plans (and, indirectly, their insurers)[29] for compliance with the ACA's insurance market reforms and other provisions of ERISA Part 7 (including MHPAEA). Importantly, DOL has announced that this enforcement initiative will focus not only whether plans have amended their governing documents to comply with the ACA, but also on the plan's *actual* operations and administration—meaning that DOL will be seeking actual claims data to verify compliance with the ACA. The DOL's audit letters to health plans are usually quite lengthy and seek documents relating to a range of issues, such as COBRA and HIPAA, but with respect to the ACA insurance market reforms, DOL letters usually seek, among other things:

- Documents related to dependent coverage up to age 26 (including plan provisions and notices sent to participants describing enrollment opportunities for any such children who may have previously ''aged out'' of coverage);
- A list of any participants who had coverage rescinded, and detailed information as to the basis for such rescissions;
- Information concerning eligibility determinations by the plan, and compliance with the ACA's 90-day limit on waiting periods;
- A list of all individuals denied coverage, or who had claims denied, because of preexisting condition exclusions codified in the plan, as well as documentation that such exclusions had been removed by the date required by the ACA;
- Information about any lifetime or annual limits that the plan imposes, including information as to how a plan determined that a particular benefit was not an ''essential'' health benefit;
- Copies of disclosure notices sent to participants regarding their choice of providers;
- Information about the plan's coverage of emergency department services and compliance with ACA rules regarding cost-sharing limits and preauthorization requirements;
- Documents describing the plan's coverage of preventive services with no cost-sharing;
- Detailed information about the plan's claims and appeals procedures, including updated notices of adverse benefit determinations and copies of contracts with independent review organizations (''IROs'');
- Claim processing and claim denial files for a representative sample of participants;
- Copies of any IRO decisions that overturned claim denials by the plan; and
- For plans claiming grandfather status, detailed information concerning the current benefits and cost-sharing provisions as compared to those in effect on March 23, 2010, and required notices to participants disclosing the election of grandfather status. This would include copies of plan documents, summary of benefits coverage and summary plan descriptions for each of the years at issues, and all meeting minutes relating to the health plan for the years in question.

C. DOL Audits of Plan and Insurers' Claims Processing Systems

Plan sponsors and insurers should also be aware that various regional offices of the DOL have recently undertaken very close reviews of the claims processing systems – both manual and automated – through which health plan benefits are adjudicated. Indeed, we have seen extremely broad document requests or subpoenas from DOL, seeking, among other things:

- Internal and external audits and quality reviews (including customer audits);
- Details regarding claims systems architecture and software, and access to full claims systems and data;

[26] HHS has expressly noted that ''[t]he vast majority of states are enforcing the Affordable Care Act health insurance market reforms.'' *See* http://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/compliance.html (last visited January 23, 2015).

[27] *Id.*

[28] If so, such review would conflict with HHS's earlier pronouncements about its intended enforcement strategy. Specifically, HHS announced that ''[b]ecause QHPs are one of several commercial market insurance products operating in State markets, HHS will seek not to unnecessarily duplicate or interfere with the traditional regulatory roles played by State DOIs.'' 78 Fed. Reg. 37032, 37060. Rather, HHS stated that it wanted ''to focus its QHP oversight to Exchange standards applicable to issuers offering QHPs (for example, correctly administering advance payments of the premium tax credits and cost-sharing reductions and offering benefits consistent with those set forth in the QHP applications approved by HHS),'' given that ''oversight of market-wide standards will generally be performed by States in their traditional regulatory roles.'' *Id.*

[29] As noted above, ERISA section 502(b)(3) provides that subject to one exception not relevant here, DOL ''is *not* authorized to enforce . . . *any requirement of [ERISA] part 7 against a health insurance issuer* offering health insurance coverage in connection with a group health plan[.]'' (Emphasis added). Given that ERISA section 715 – which incorporates the ACA's insurance market reforms into ERISA – is included within part 7 of ERISA (as is MHPAEA), it follows that section 502(b)(3) also bars the DOL from directly enforcing those ACA reforms (and MHPAEA) against health insurance issuers that provide insured coverage to group health plans. But DOL can enforce the ACA against group health plans that purchase group health insurance, who will then notify the insurer of the DOL's findings of non-compliance, perhaps triggering a change in the terms of the insurance product or the manner in which it is administered.

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■ Claim and appeal processing and procedure manuals;

■ Claim litigation files;

■ Information regarding customer, participant, and health care provider complaints;

■ Copies of all guidelines, manuals and standards (such as medical guidelines) used by the plan or insurer as part of the claims or appeal process;

■ Information regarding the compensation, training, and performance evaluations for all personnel involved in the claims and appeal process; and

■ Interviews with line and supervisory personnel at all levels of the claims and appeals process.

V. Responding to an HHS or DOL Investigation

Given the increasing frequency of health plan audits and the enormous amount of time and resources that could be incurred in responding to an HHS or DOL investigations, plans and insurers should proactively take steps to prepare for a federal agency audit. These steps include:

■ Maintaining a centralized file (both electronic and hard copy) of all:
—Plan documents (including insurance contracts)
—Plan amendments or resolutions amending plan terms
—Meeting minutes that discuss potential changes to plan terms
—Summary Plan Descriptions (SPDs)
—Summary of Benefits and Coverage (SBCs)
—Service provider contracts
—Reports of benefit consultants or brokers discussing compliance issues
—Memoranda from legal counsel discussing legal requirements imposed on the plan and the plan's compliance with such laws
—Participant disclosures required by the ACA and other provisions of ERISA
—Stop-loss policies
—Fidelity bonds
—Fiduciary liability insurance

■ Conducting periodic internal compliance reviews, and correcting any errors identified.
—DOL has published a 68-page ''compliance checklist'' that provides a helpful roadmap of the broad range of health plan issues that DOL investigates, which should be helpful to many plans and insurers in preparing for an audit.[30]
—Note: proactively correcting any identified errors before a government investigation commences should expedite the audit process and mitigate the risk of adverse finding and potential penalties.

■ Consulting with experienced ACA and MHPAEA counsel upon receipt of a DOL or HHS audit, to work with the agency in narrowing the scope of information sought and establishing a rolling production schedule, and to provide technical expertise to assist in responding to the regulators' inquiries and concerns.

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[30] http://www.dol.gov/ebsa/pdf/cagappa.pdf (last visited January 26, 2014).