Lewandowski v. Johnson & Johnson

Chapter Three: Where Oh Where is the Plan Document – Summary Plan Description…

In Chapter 1, we provided an overview of this impactful prescription drug plan lawsuit. We identified the claims presented and highlighted one claim in particular. One of Plaintiff's claims includes an allegation that J&J ("J&J"), a company with over 130,000 employees, failed to produce the requested Plan Document and Summary Plan Description for the J&J Prescription Drug Component Plan of the J&J Group Health Plan (the "J&J Rx Plan"), upon request by the Plaintiff.

In Chapter 2, we evaluated the defenses raised by J&J to the original complaint. We highlighted various defenses that J&J was pursuing to defend against Plaintiff's allegations.

We noted in Chapter 2 that J&J filed a motion to dismiss the lawsuit, which is not unexpected at this juncture. The Motion came with a memorandum in support that included what was asserted to be the J&J Rx Plan Document and Summary Plan Description ("SPD"), along with J&J's asserted defense that there was no written request that required it to respond by producing these documents.

In this Chapter, we take the opportunity to review what J&J asserts is the applicable J&J Rx Plan document, as required by ERISA Section 402, and SPD, as required by ERISA Section 102 ("Plan Document/SPD"). Consistent with our comments in Chapter 1, where we highlighted that in most cases, prescription drug benefit plan sponsors have not adequately prepared and presented the prescription drug rules for benefit plan management through appropriate and intelligent documentation, the J&J Plan Document/SPD was, perhaps not surprisingly, grossly inadequate and incomplete.

In this Chapter 3, we will have some "ERISA fun" by evaluating the J&J submitted documents under our standard prescription drug plan Compliance Checklist.

All benefit plans, including prescription drug plans, must establish and communicate the rules for how such plans operate. It's not just a matter of "compliance." Of course, there are specific legal requirements. But, our assessment includes other important aspects of these documents. Plans, like the J&J Rx Plan are managed, and benefits are delivered through a set of rules. If the "rules of the road" are not established and well communicated, the result is not only inefficiency, but such a failure prevents proper administration and management of these important benefits. So, our Compliance Checklist review of the terms and the noted defects that we observe in the J&J Rx Plan Document/SPD are very important to the proper functioning of this benefit plan. The failure to establish and communicate rules in a reasoned fashion speaks to a failure to manage and a potential failure of the required fiduciary functions related to the J&J Rx Plan.

What Was Submitted….. Really, is this it?

Overview of Fundamentals - Our examination begins, as it routinely does, with our Prescription Drug Compliance Checklist. The Checklist aids in our assessment of certain essential rules, including how the documentation incorporates all of the relevant materials, booklets, supplements and schedules, the identification of plan funding, the designation of the fiduciaries, and the

inclusion of important default language. Notably, certificates, booklets and flyers alone, prepared by insurers, consultants and others, are not necessarily designed to fully comply with the core ERISA requirements, or to identify all of the rules and protect the plan constituents, including the employer and the covered persons. For example, an insurance certificate will generally not include appropriate claims procedure language for items that are outside the scope of the insurer's function, such as eligibility, or what to do if a covered person is overpaid, or commits a fraud related to dependent coverage. Of course, a plan document is essentially a specialized contract, and as such, it has to be executed and adopted in accordance with the normal procedures of the Employer entity.

The SPD, a reporting and disclosure document with requirements that are different from those of a Plan document, is often easier to create, because regulations issued by the U.S. Department of Labor, at 29 C.F.R. §2920.102-3, contain a checklist of sorts, with a listing of the SPD requirements. Of course, ERISA attorney analysis and industry standards come into play when creating legally sound and appropriately worded rules in this context.

A word about default language is important. There are really three main areas where a group benefit plan must include default language to identify rules that protect all concerned. As noted above, the first is with respect to the designation and role of the fiduciaries of the group benefit plan. In the context of group benefits, we often have claims administrators that are either third party administrators, or insurers. These entities have defined roles, but those roles are almost never all encompassing. As such, the Plan terms must provide guideposts as to the fiduciary roles.

In this regard, a default claims procedure is also critically important. The employer, or committee of the employer is almost always responsible for certain basics, such as eligibility, addressing participant payment of required contributions, duplicate or overpayments, fraud and other issues. As such, a default claims procedure is a must, so that the employer has a procedure to follow when its administrative functions are at issue relative to a claim.

Other default language is needed because certain forms of benefits are delivered by insurers or other third parties. Sometimes odd facts arise, such as when an employer makes and eligibility error, or an employee fails to notify the employer of a status change. In these cases, default COBRA language is also essential.

An assessment of the J&J Rx Plan documentation is revealing and also a bit surprising.

The Plan Document – What It Includes - Turning to the results of our checklist process, we start with the content of the Plan Document. The Plan Document identifies itself as the Plan Document and incorporates by reference the "Component Summary Plan Descriptions" and Insurance Contracts referenced in a Schedule A. This a good start, because we commonly see the incorporation of certificates, booklets and other benefit plan descriptions as part of the overall plan construct.

The Plan Document includes some definitions, although they are very limited. Some information about eligibility and coverage is included. Funding is identified, including the fact that unless insured, the Component of the Plan is self-funded. The Plan also notes that the Employer will create a trust fund. This is a reference to the Voluntary Employee Beneficiary Association trust

("VEBA") that is part of this Plan's funding structure and that is used to help fund the sizable benefit spend involved. That said, it does not appear that the VEBA's existence actually impacts the overall claims in this case.

The Plan Document refers to COBRA coverage and Claims Process, but those provisions refer to the Component SPDs. Whether the Component SPDs have appropriate default language is not evidenced from the submitted documents.

Finally, the Plan Document has general references to Administration, including the identification of the Plan Administrator and Service Administrators, but does not focus on language to delineate between the two. Discretionary authority language is provided along with certain liability limits and indemnification. Finally, the Plan Document includes amendment and termination provisions, and states the applicable law.

Overall, I would describe the group plan document as skimpy and heavily reliant upon the Component SPD documents, most of which were not provided with the filing.

The Prescription Drug Component SPD – What it Includes. Turning to the Prescription Drug Coverage Details Supplement (the "Rx Supplement"), this document consists only of sixteen (16) pages. Eleven (11) of these pages address non-Medicare terms and the balance for Medicare eligible persons. Additionally, the Rx Supplement includes a title page and table contents. Our compliance checklist for a prescription drug benefit plan does not include a score for the number of pages, but even at a quick glance, it appears clearly light in terms of the presentation of rules and management guideposts.

In the Introduction, the Rx Supplement makes clear that it incorporates the terms of the six (6) different J&J group medical plans. As such, the Rx Supplement is to be taken together with these reference group medical plan Component SPDs. However, the group medical plan Component SPDs were not submitted with the Defendants' Motion to Dismiss. As such, the documentation submitted to the federal court along with a critical dispositive motion is not technically complete. That said, we would find it interesting to see a substantial volume of prescription drug benefit rules, definitions and more, in a group medical plan Component SPD that does not itself provide for prescription drug coverage.

Turning to the content of the Rx Supplements, a benefit "Service Center" is listed and details on how to contact that benefit Service Center are provided. It's unclear as to whether the benefit Service Center can connect the covered person to Express Scripts as the pharmacy benefit manager ("PBM") or the designated specialty medication provider, Accredo Health Group. But, later in the Specialty Medication section, Express Scripts' telephone number is listed, but only a telephone number. It does not include an email or mailing address. It does not identify where claims or claim appeals are to be submitted. We note below that this is problematic from the perspective of the claims procedures.

Eligibility provisions are noted to be tied to the eligibility provisions under an existing J&J group medical plan, that is listed in the Rx Supplement.

The Rx Supplement contains information about deductibles and coinsurance, and details the differences in such amounts amongst the different group medical plan offerings. Rules on out-of-pocket maximums are also provided, but unless you have the applicable J&J group medical Component SPD handy (again, these were not provided along with the Motion), you cannot understand the J&J Rx Plan rules. Supply lines through retail and home delivery are noted, and if a covered person wishes to know if a pharmacy is a participating pharmacy, they can contact Express Scripts to find out. We again note that contact information on Express Scripts is limited.

There are specific terms that relate to the coverage and access to certain types of drugs. Non-sedating antihistamines and proton pump inhibitors have special terms. There are certain medications that are covered at 60%. Those are specifically referenced, and a list of them is purportedly available on the Express Scripts website, but again, contact information is limited.

Other specific medications addressed include contraception, drugs, tobacco cessation, compound medications, and special terms that apply to Specialty Drugs. Notably, drugs manufactured and marketed by J&J, are subject to a special discount and special terms. There is no mention of specific formularies and the term formulary is absent from the Rx Supplement. See more on this below.

The lawyers for J&J did not submit any of the medical plan Component SPDs. As such, we cannot, and the federal court cannot make a full assessment of the documents that were presented as constituting the J&J Rx Plan, Plan Document/SPD. Certainly, what is included in the Rx Supplement is limited.

Where Oh Where Are The Rules…. What is Clearly Missing

Having just covered what is contained in the Rx Supplement, the reader may be left with the thought: "Is that it?" This author has the same thought. Although we noted in Chapter 1 that when employers separate the delivery of group health benefits and prescription drug benefits, there has been a lack of good documentation, we would have anticipated more from a company like J&J. While the incorporation of Component SPDs for group health plans into and to be read in conjunction with the Rx Supplement is not wrong, the Rx Supplement appears to be missing key features that are not likely included in the Component SPDs.

That said, the documents submitted raise a lot of questions. So, let us turn to the terms and provisions that we would expect to see, and perhaps in future filings, we will see.

As noted, it is critically important in the delivery of pharmacy benefits to set rules and thereby manage the prescription drug benefits delivery, so that the appropriate and medically necessary drugs are delivered, at a reasonable price, to the covered persons who actually need them. There are a number of pressure points in the delivery of pharmacy benefits that need to be addressed. These include higher cost medications, such as specialty and orphan medications, that require focused and solid management. This means the establishment and communication of appropriate rules to avoid a multitude of problems.

In reviewing Plan Documents and SPDs for the rules and management terms, our standard Prescription Drug Group Benefit Plan Compliance Checklist includes approximately 80 items. Some have subparts, such as eligibility and definitions. For example, we generally check for fifteen (15) important definitions, to ensure that important terms are clearly defined. Our review of the J&J Rx Supplement revealed that approximately seventeen (17) items were covered by the documents presented. This constitutes approximately 21% compliance. There are another seven (7) provisions, that were present in some manner, but probably could have been augmented or presented in a better way. That constitutes another 10%. And as such, our overview suggest that there are approximately 30% of the rules and provisions that we would like to see, presented in the Plan Document and Rx Supplement. Of course, we note that the Component SPDs are to be considered alongside the Rx Supplement, but in many instances, we have to be doubtful that the group medical plan Component SPD will have a number of these terms.

Some of the items missing are likely to appear in the Component SPDs. For example, we would expect the Component SPDs to include: a statement of a ERISA rights; coverage and coverage termination, applicable law; possibly terms to address fraud or concealment; provisions that reference inconsistencies between documents; subrogation; duplication of benefits; and references to HIPAA, USERRA and FMLA. Without the actual component SPD and insurance contracts, we can't be sure, but we would expect these types of terms to be contained in the Component SPDs. This would reduce the missing in our Compliance Checklist to about forty (40) items, which constitutes about 50% of the expected and required terms.

The Plan Document attempts to address fiduciary authority, but we do not believe it actually passes muster here. Since Express Scripts administers prescriptions as the PBM, and Accredo Health is involved in Specialty Medication delivery, these entities will be the claims administrators for prescription drug benefits. We know that the Benefit Committee is not administering the day-to-day items under the J&J Rx Plan, so the rules that make Express Scripts and/or Accredo Health responsible must be clearly established by the presented documentation. Notably, no mention of Orphan Drugs is included.

There is no reference to controls and management through the development and use of a formulary. The word "formulary" does not appear in the Rx Supplement. In this regard, the documentation fails to properly articulate a definition for the term "specialty medication." There is a general, vague definition in the Rx Supplement, but specialty medication is not an official Food and Drug Administration term. It is an industry standard term. As such, specialty drugs are normally determined and classified by PBMs through formularies. Missing entirely are references to Orphan Drugs, which are specifically defined by the FDA. And Orphan Drugs are often ridiculously expensive. But, the generalized definition of "typically used to treat chronic, complex conditions, such as cancer, growth hormone deficiency, hemophilia… etc." is not clear and may encompass in its scope items that are really not Specialty Drugs, or exclude some that should be included. Right now, the standard is the use of a formulary of Specialty Drugs and providing particpants easy access to it. The Rx Supplement fails this standard.

We have noted that unless the Component Plans include a default claims procedure this is a defect. Also, COBRA coverage should also be tied to prescription drug benefit delivery under the J&J Rx

Plan. It is not in the documents presented, but may be in the Component Plans. This would improve the compliance assessment of these documents.

Other important items that are likely missing, include the following:

- Definitions - A number of definitions, including formulary and formulary access, maintenance medication, prior authorization, step therapy, and related terms
- PBM Contact Information - Detailed contact information for the pharmacy benefit manager, including claim appeal information with respect to the PBM and, in this case, the Accredo Specialty Drug manager
- Embed Deductibles - Clarity on whether or not the individual deductible is embed into the family deductible
- Formulary definition and how to access the Formulary
- Exclusions – A specific listing of exclusions. Most prescription drug plans have over thirty (30) exclusions
- Specialty Access - Special language for access of Specialty drugs, including Accredo Health
- Medical Related Reviews - Utilization review and Step Therapy processes
- Clinical trials – access
- Dispense as Written – appropriate terms
- Paper Claims – whether there is a process and how to submit paper claims
- Claims Administrator – integration of the claims administrator in the plan claims process as compared to the Committee's role as lead fiduciary, needs to be clarified and improved
- Coverage termination
- Time limits on the submission of claims
- Limitation on filing legal action
- Recovery of overpayments
- Coordination of benefits
- Subrogation
- Access to records
- And more….

Findings Are Incomplete But Show Material Gaps – Complete Self-Contained Documentation is Better

Unfortunately, the Rx Supplement and Plan document for the J&J Rx Plan leave us wanting for more. It is possible that the Component SPDs include more to reduce the list of missing items, but we would find it unusual that the group medical plan Component SPDs would contain all of the core terms and conditions that we would expect to see in a prescription drug Plan Document and SPD.

Ultimately, we may learn more as this case proceeds, but based upon this assessment, the J&J Rx Plan documentation is sorely inadequate and fails to provide the guidelines and rules of the road

necessary to communicate how the J&J Rx Plan is supposed to function, to provide valuable benefits and protect the interests of all concerned.

Importantly, unlike the Doc*Smart* Rx product from EZ ERISA, which includes a self-contained full Prescription Drug Plan Document/Summary Plan Description, even if the J&J Component SPDs include additional information, it is harder for the user and likely harder for the claims fiduciaries to administer to rules that are in so many documents. Overall, there are likely clear gaps, which makes the J&J Rx Plan documentation deficient in many respects. (Note the Author is the founder and President of EZ ERISA, and see www.ezerisaplan.com for more information).

What Next?

As we write, the First Amended Complaint was just filed and we will scour it for new assertions and new statements of claims in Chapter 4. And, we can already see the Defendant, J&J is warming up its updated motion to dismiss.

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