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HEALTH & WELFARE PLAN LUNCH GROUP

November 5, 2020

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INDEX

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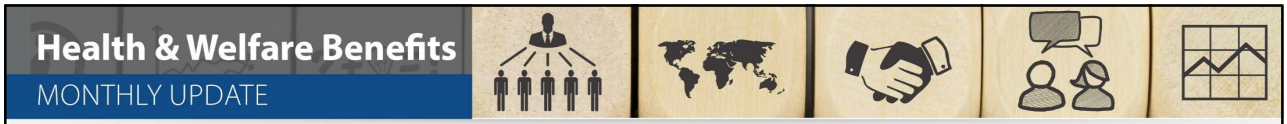
1



Agenda

- Post Election Rundown
- Final Health Plan Transparency Rules
- Litigation Update
- Recap and Update on Tolling period and COVID Guidance Developments

2

Health & Welfare Benefits
MONTHLY UPDATE

Post Election Rundown

- Election Rundown
- Impact of Election on Further COVID Relief
  - Health benefit issues in play
- Outlook for Further Health Benefits Legislation and Regulatory Activity

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3

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Final Rule on Transparency in Health Care Coverage for GHPs

On October 29, 2020, CMS along with the DOL and the Treasury issued a final rule (F.R.) on price transparency purposed toward enabling patients to accurately anticipate their healthcare costs in order to make fully informed and value-conscious decisions.

Not to be confused with HHS hospital price transparency rule finalized in 2019. That rule is in litigation:

- Federal district court judge upheld;
- US Court of Appeals for D.C. Circuit heard arguments on October 15, 2020, but has yet to issue a ruling.

F.R. overlaps HHS hospital price rule to some degree, but more expansively covers the entire health-care industry.

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4

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Final Rule – Required Content

Regarding disclosure to participants:
- Estimated cost-sharing liability for a covered item or service.
- Accumulated amounts
- Negotiated rates expressed in a dollar amount
- OON allowed amount
- Items and services content list
- Notice of prerequisites to coverage
- Disclosure Notice with specific explanations (i.e., balance billing; actual charges deviation from estimate; estimate not guarantee of coverage; and additional information/disclaimers that plan/issuer determine necessary)

Regarding public disclosure:
- Plan/coverage identifier
- Billing Codes
- In-Network Applicable Amounts; OON allowed amounts; or Negotiated Rates and Historical Net Prices for Rx Drugs

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Final Rule: Modifications following Proposed Rule

Revised definition of "negotiated rate" to mean the amount a plan or issuer has contractually agreed to pay for a covered item or service, whether directly or indirectly through a TPA or PBM, to an in-network provider (including an in-network pharmacy or other prescription drug dispenser), for covered items or services.

Two key aspects to change:
- The term "third party" from the proposed definition was expanded in the F.R. to explicitly refer to "third-party administrator or pharmacy benefit manager."
- The final definition of "negotiated rate" specifically notes that the term in-network provider includes an in network pharmacy or other prescription drug dispenser

Completely new definitions for: "billed charge," "copayment assistance," "derived amount," "historic net price," "national drug code," and "underlying fee schedule."

Prescription drug file added to paragraph (c) requirements.

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Final Rule: Two Approaches

F.R. achieves goals through two approaches applicable to non-GF plans:

- First Approach: Make available to participants, beneficiaries and enrollees (or their authorized representative) personalized OOP cost information, and the underlying negotiated rates, for all covered health care items and services (including Rx drugs) through an internet-based self-service tool and in paper form upon request.
  - Initial list of 500 shoppable services will be required to be available via the internet based self-service tool for Plan Years (PYs) that begin o/a January 1, 2023.
  - Remainder of all items and services will be required for these self-service tools for PYs that begin o/a January 1, 2024.

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Final Rule: Second Approach

Make available to the public, including stakeholders (i.e., consumers, researchers, employers, and third-party developers), three separate machine-readable files that include detailed price information.

- In-network Rate File showing "negotiated rates" for all covered items and services between plan or issuer and in-network providers.
- Allowed Amount File showing both the historical payments to, and billed charges from, OON providers.
  - "Historical payments" must have a minimum of twenty entries in order to protect consumer privacy.
- Prescription Drug File detailing the in-network negotiated rates and historical net prices for all covered Rx drugs by plan/issuer at the pharmacy location level. [Also an addition to Proposed Rule]

Note: Plans and issuers must display these data files in a standardized format and update the files monthly. Provisions regarding public disclosure apply for PYs beginning o/a January 1, 2022.

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MONTHLY UPDATE

Final Rule: MLR Credit for "Shared Savings", Relief, and HIPAA

F.R. incentivizes insurers to encourage patients to shop for providers offering lower cost services with higher value and share those savings by allowing insurers to take credit for such "shared savings" payments in their medical loss ratio (MLR).

- MLR is the percentage of a premium that an insurer spends on services that improve care quality, and insurers have to pay rebates if they don't meet a certain threshold.

F.R. provides unnecessary duplication relief: If an issuer of insurance has a written agreement with the GHP to provide the information, and the issuer fails to do so, the violation would apply to the issuer and not the plan. Although F.R. enables the use of third-party entities, it expressly denies similar relief for plans/sponsors who enter into such written contract with parties "other than issuers."

Privacy, Security, and Accessibility: F.R. does not intend to alter privacy and security requirements, but it indicates that the rules would not establish any new groups of persons/entities who are authorized to access and receive PHI under these requirements. Existing laws and rules w/r/t "authorized representatives" would continue to apply.

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Final Rule: Final Notes

The following would not expressly be considered a failure to comply with the new requirements:

- Errors/omissions in a disclosure that are corrected as soon as practicable.
- A temporarily inaccessible website provided that the plan/issuer makes the information as soon as practicable, and
- If a plan/issuer relied in good faith on information from another entity unless the plan/issuer knew/should have known that the information was incomplete/inaccurate.

F.R. relies on legal authority granted by the ACA

- If ACA completely invalidated, the F.R. will fall as well.

The Departments note that the F.R. is intended to be similar to the information that generally appears on explanations of benefits (EOBs). Only anticipated items/services that a person could incur are required by the F.R.

- Because insurers and plans are required to supply this information after a beneficiary receives the services, requiring the same info in advance of receiving the services should not elevate the risk of releasing proprietary information.

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MONTHLY UPDATE

LITIGATION UPDATE

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11

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California v. Texas Constitutionality of the ACA

- The 2017 Tax Cuts and Jobs Act (TCJA), set the individual mandate penalty to $0 as of January 1, 2019.
- Texas filed suit in federal district court arguing the individual mandate was now unconstitutional and since that mandate was essential to the ACA as a whole, the entire ACA was unconstitutional.
- District court agreed with Texas ruling the ACA unconstitutional (stayed pending appeal).
- The U.S. Court of Appeals for the 5th Circuit affirmed the district court's decision that the individual mandate was unconstitutional but sent the case back to the district court on whether the other provisions of the ACA were severable from the individual mandate and therefore survived.

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12

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California v. Texas
Constitutionality of the ACA

- In the interim the Supreme Court agreed to review the case.
- Argument is scheduled for November 10, 2020.
- Decision expected in the summer of 2021, but could be earlier (March, April)
- Number of possible outcomes.
  - Dismiss the case on procedural grounds (e.g., standing) and the ACA remains as is (not likely).
  - Uphold the ACA.
  - Find the individual mandate unconstitutional but determine the rest of the ACA is "severable" from the individual mandate so the ACA stands as is.

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California v. Texas
Constitutionality of the ACA

- Number of possible outcomes.
  - Find the individual mandate unconstitutional as well as related consumer protections such as "guaranteed issue," "community rating", ban on pre-exiting conditions, etc. But other provisions like Medicaid expansion and the employer mandate (pay or play) are severable and remain as is.
  - Find the individual mandate unconstitutional but, like the Fifth Circuit, remand the case back to the district court to determine what, if any, parts of the ACA are severable from the individual mandate-- so the ACA stands "as is" at least until the case can works its way back through the courts (unlikely).
  - Agree with the district court that the entire ACA is unconstitutional.
  - Any decision holding anything other than the mandate unconstitutional may give Congress an opportunity to adopt new legislation to prevent disruption.

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Rutledge v. Pharmaceutical Care Management Association
ERISA Preemption of State Pharmacy Benefit Manger (PBM) Regulation

- PBMs set the price plans will pay a pharmacy for each generic drug by reference to a document that establishes a maximum allowable cost ("MAC.)"
- Pharmacies claim that PBMs are setting MAC below any pharmacy's attainable acquisition cost.
- In 2015, Arkansas passed "Act 900" which regulated PBM reimbursements and required reimbursement tied to certain acquisition cost standards.
  - Required certain administrative procedures for PBMs like updating MAC lists and certain appeals processes relating to disputed reimbursement claims.
- ERISA preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan."

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MONTHLY UPDATE

Rutledge v. Pharmaceutical Care Management Association
ERISA Preemption of State Pharmacy Benefit Manger (PBM) Regulation

- Eighth Circuit found Act 900 is preempted and the Supreme Court agreed to review the case.
- The Supreme Court has struggled over the years on this incredibly broad statutory preemption language and any constraints on this language.
- Argument on October 6, 2020 where the Supreme Court focused on two prior decisions.
  - New York State Blue Cross Plans v. Travelers Ins.—States can generally regulate hospital prices even though those prices might ultimately be passed on to an ERISA plan.

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MONTHLY UPDATE

Rutledge v. Pharmaceutical Care Management Association
ERISA Preemption of State Pharmacy Benefit Manger (PBM) Regulation

- Gobeille v. Liberty Mutual -- ERISA preempts a Vermont statute that established reporting and disclosure requirements for health plans.
  - In Gobeille Justice Thomas questioned whether ERISA preemption, if taken at face value, is constitutional.
- Hard to tell where the case will come out with just reviewing the arguments.
  - Clear the Justices are still struggling with the parameters of preemption.
- 45 states have some type of regulation of PBMs with some very similar to Arkansas.
- Decision could implicate other types of state provider regulation as well.

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Out-of-Network Providers' Claims and ERISA Preemption

- These claims are separate from claims that the out-of-network provider received an assignment from an ERISA plan participant or beneficiary.
- Complaints intentionally avoid any mention of ERISA.
- We have seen a dramatic increase in these types of claims.
- Claims are based on what an insurer or plan allegedly said over the phone or through an e-mail to the out- of-network provider. This includes any preauthorization of the procedure or negotiation over the claim.
- Sometimes there is a mention of a schedule of benefits associated with an ERISA plan with respect to pricing of the claim.

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MONTHLY UPDATE

Out-of-Network Providers' Claims and ERISA Preemption

- Claims are based on a state law written or oral contract theories, promissory estoppel or other types of related state law causes of action.
- Courts have generally found these claims not to be preempted
- As opposed to in-network providers, the courts have noted that there is no obligation of the out-of-network provider to provide care and no promise by the plan directly to the out-of-network provider that it will be reimbursed for the care.
- Similarly the out-of-network provider has not agreed that any reimbursement will be limited by the terms of an ERISA plan.
- Courts have noted that out-of-network providers are therefore not parties to the "ERISA bargain."

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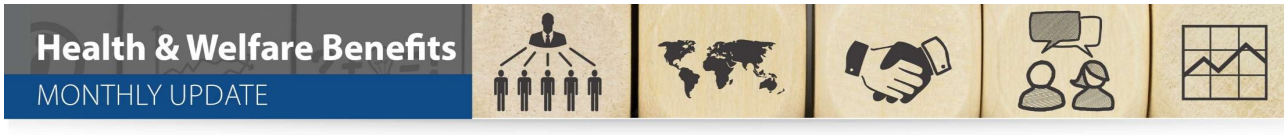
MONTHLY UPDATE

Out of Network Providers' Claims and ERISA Preemption

- Cursory reference to an ERISA schedule of benefits or the fact that an insurer/plan pre-authorized the procedure is not sufficient to trigger preemption.
- Recent decision from the Third Circuit holding such claims are not preempted but there are prior decisions form the Second, Fifth, Seventh, Eighth, Ninth, Tenth and Eleventh Circuits.
  - Sixth Circuit somewhat of an outlier.
- These decisions are very fact specific and look to the terms of the complaint that is filed. The decisions, generally, simply decide that the claim can go forward without deciding whether there was actually a breach of contract or broken promise supporting a promissory estoppel claim.



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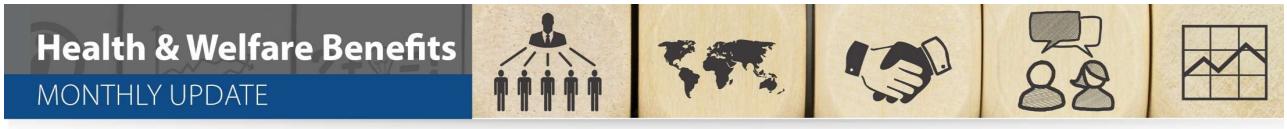

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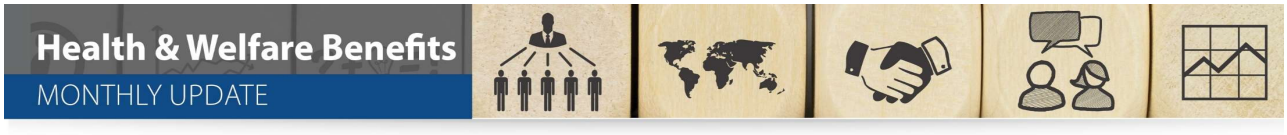
DaVita, Inc. v. Marietta Memorial Hospital Employee Health Benefit Plan (6th Cir. Oct. 14, 2020) --Network Exclusion of Dialysis Providers

- Several cases where all dialysis providers were either treated as out-of-network or at their own separate reimbursement tier (e.g. 125% of Medicare)
- Dialysis providers argue that this plan design is intended to force participants off the group health plan (GHP) and on to Medicare where the GHP would ordinarily be primary to Medicare for End-Stage Renal Disease (ESRD)
- If individual is covered under a GHP, Medicare is secondary to the GHP for ESRD during a 30 month coordination period.
- Dialysis Providers argue that such GHP provisions violate two provisions of the Medicare Secondary Payer (MSP) statute.
  - The design "takes into account" that an individual is entitled to or eligible for" Medicare based on ESRD.
  - The design differentiates in the benefits it provides between individuals having ESRD and other individuals covered by such plan on the basis of . . . the need for renal dialysis, or in any other manner.

Health & Welfare Benefits
MONTHLY UPDATE

DaVita, Inc. v. Marietta Memorial Hospital Employee Health Benefit Plan (6th Cir. Oct. 14, 2020) --Network Exclusion of Dialysis Providers

- GHP's argument has been that the design treats all dialysis the same without regard to whether a person has ESRD or is eligible for Medicare.
  - GHPs were largely successful at the district court level.
- Very complex arguments on whether a provider has "standing" to bring a MSP claim.
- In mid-October, the 6th Circuit reversed a federal district court that had dismissed the claims and let the case go forward.
  - Case can go forward on both MSP theories.
  - Does not mean the dialysis provider is going to succeed in its case, just that they have stated a plausible cause of action.



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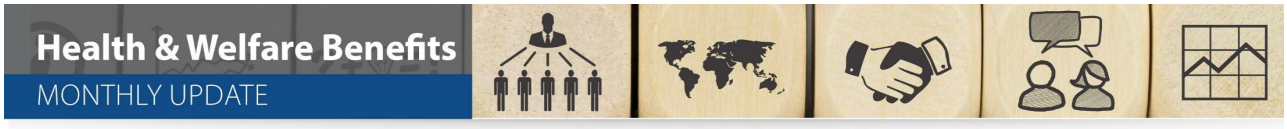

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Health & Welfare Benefits
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DaVita, Inc. v. Marietta Memorial Hospital Employee Health Benefit Plan (6th Cir. Oct. 14, 2020) --Network Exclusion of Dialysis Providers

- Two other cases (where the GHPs were successful in having the claims dismissed) were argued before the 9th Circuit on October 8, 2020:
  - DaVita, Inc. v. Amy's Kitchen, Inc., and DaVita Inc. v. Va. Mason Mem'l Hosp.
- Upshot is that plan designs that exclude dialysis providers from the network or place them in their own reimbursement "tier" are being challenged and litigation is ongoing.

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Assignment and Authorized Representatives

- McKennan v. Meadowvale Dairy Emp. Benefit Plan, 2020 WL5085954 (8th Cir. 2020)
  - Plan Administrator rescinded coverage after participant used false name and social security number when enrolling in plan. Participant died and did not appeal rescission.
  - Hospital/Provider appealed coverage rescission as an assignee.
  - Plan denied provider's right to appeal because the provider was not formally designated as the participant's authorized representative.
  - Plan specifically stated that assignment of benefits would not constitute appointment of assignee as authorized representative.
  - Plan also required participants to exhaust all levels of appeal before filing suit in court.

Assignment and Authorized Representatives

- Court held that assignee of a participant in an ERISA plan may sue to enforce rights or recover benefits if the assignment is not prohibited.
  - Plan terms prohibited assignment of benefits but not causes of action after the benefit denial.
- Court held that cause of action against the plan accrues after final denial of internal appeals.
- Provider did not exhaust internal appeals because it was not the authorized representative and could not appeal rescission on behalf of deceased participant.

25

Authorized Representatives

DOL Information Letter 02-27-2019

- An ERISA plan may establish reasonable procedures for determining whether an individual has been authorized to act on behalf of a claimant.
- Procedures cannot prevent claimants from choosing for themselves who will act as their representative.
- Plans must include any procedures for designating authorized representatives in the plan's claim procedures and in the plan's summary plan description or a separate document that accompanies the SPD.

26

Wilderness Therapy

- What is Wilderness Therapy?
  - Services range from teaching camping and survival skills to holistic therapies in an outdoors setting.
  - Services usually provided to teenage dependents.
- To survive a motion to dismiss, many courts allow plaintiffs to argue "as applied" violation of MHP Act rather than a facial violation.
- Evaluate whether plan equally covers mental health/substance use disorder benefits and medical surgical benefits at intermediate facilities such as residential treatment centers.
- If plan wishes to exclude all wilderness therapy or some therapies, include specific provisions outlining the plan's treatment of wilderness therapy.
  - General exclusions for custodial care or educational services likely not enough to dismiss claim at the motion to dismiss stage.
- Trend in some district courts is to allow expanded discovery outside of the "administrative record" generally applicable to ERISA cases.

27

Thank you!

28