Health Policy Regulation Webinar for Employers

Thursday, October 14 | 9:00am – 10:45am

The Alliance
Self-Funding Smart®

Introduction

The Alliance
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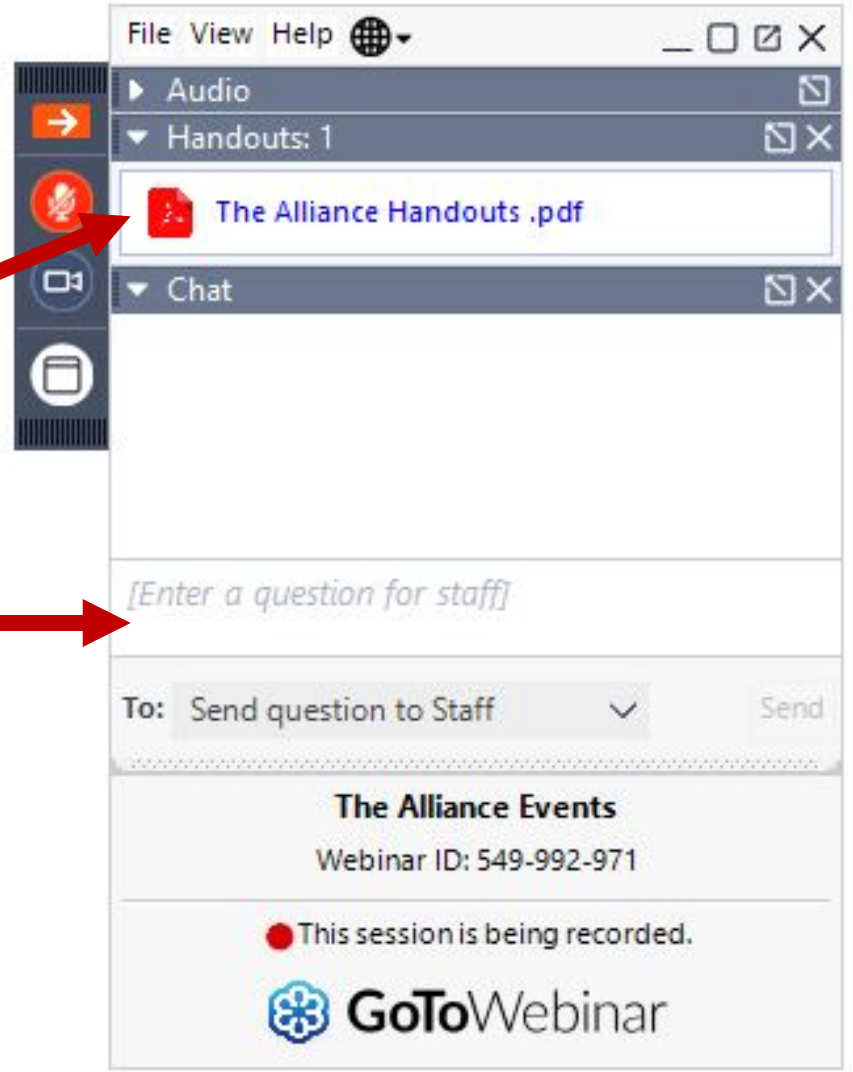

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Health Policy Regulation for Employers

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October 14, 2021

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Agenda

- Overview of new changes
- Requirements related to Surprise Billing and No Surprises Act ("NSA")
- Re-publication of certain "patient protection" regulations
- Other Consolidated Appropriations Act ("CAA") changes
- Other legal changes / updates

Overview of New Changes

- Rising medical costs are not a new story
- Congress has tried various ways to control costs
- Price transparency at national level important goal
  - The Alliance has been active in this area previously
- Idea is that forcing all the "players" (health care providers; insurers; TPAs; PBMs) to reveal their negotiated costs (for in-network providers) and typical costs (for out-of-network providers) will foster greater competition
- Will greater price transparency drive down costs? Or will it enable providers to compete less on price?

No Surprises Act ("NSA"), Part of CAA

- Debate over how to handle out-of-network medical claims, especially where enrollee did nothing "wrong."
  - E.g., Plan member wants to go in-network for a surgery. Finds an in-network hospital and in-network surgeon. Has surgery done, but unexpectedly a specialist (anesthesiologist) is out-of-network. Should member be required to pay for out-of-network services? What should plan pay for the out-of-network provider, because plan has no contract in place with that provider?

NSA: New Regulations

- Details of what was required was uncertain
- Interim final regulations published July 13, 2021 (IRS, DOL, HHS)
- Effective for plan years starting 1/1/2022
  - Modest hope for a delay is not going to happen for these regs

NSA: New Regulations

- Will require coordination between plan and provider
- Enrollee could, in theory, waive NSA protections and allow provider to balance bill the enrollee
  - Maybe because it's an out-of-network service, but enrollee wants to use that particular doctor
- Unless plan receives information that enrollee has provided that waiver to the provider, plan must assume that enrollee has not waived NSA protections

NSA Protections – Five Main Items

- 1: Provide protections against balance billing and out-of-network cost sharing for:
  - Emergency services
  - Non-emergency services furnished by nonparticipating providers at certain participating health care facilities
  - Air ambulance services furnished by nonparticipating providers of air ambulance services
- 2: Prohibit certain balance billing by such providers

NSA Protections – Five Main Items

- 3: Require disclosures of federal and state patient protections against balance billing
- 4: Recodify certain patient protections of the ACA and apply them to grandfathered health plans
- 5: Create complaint / audit process for violations of the protections against balance billing and out-of-network cost sharing

NSA Protections – Five Main Items

- Many new definitions
  - E.g., "air ambulance service", "independent freestanding emergency department" ("IFED"), "nonparticipating emergency facility" ("NEF"), etc.
    - IFEDs do not include urgent care centers (even if licensed by state as IFEDs), but agencies seek comments on that point (i.e., it might change)
  - Will cover as relevant for the particular topic
  - In general, make sure your plan documents / SPDs / vendors (e.g., TPA) comply with these new definitions

Surprise Medical Bills for Emergency Services

- If plan provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an IFED, plan must cover "emergency services"
  - "Emergency services": medical condition, acute symptoms of sufficient severity that a "prudent layperson, who possesses average knowledge of health and medicine", could reasonably expect absence of immediate medical attention to result in serious jeopardy, serious impairment to bodily functions or serious dysfunction of bodily organ or part
  - Definition seems to be a "win" for patients / providers, as some insurers / TPAs had tried to tried to apply more of an "expert" determination
    - Enrollee goes in for a heart attack, but it's just heartburn
  - Also includes certain post-stabilization services

Surprise Medical Bills for Emergency Services

- Plan must provide coverage for emergency services:
  - (1) Without need for any prior authorization determination
    - Even if service is provided out-of-network
  - (2) Without regard to whether the provider is a participating provider or a participating emergency facility for that service
  - (3) Without limiting what constitutes an emergency medical condition solely on the basis of diagnosis codes
  - (4) Without regard to any other plan term or condition, other than:
    - (a) Exclusion or coordination of benefits
    - (b) An affiliation or waiting period
    - (c) Applicable cost-sharing

Surprise Medical Bills for Emergency Services

- (5) If service is provided by a nonparticipating provider or a NEF:
  - (a) Not impose any "administrative requirement or limitation" that is "more restrictive" than the requirements or limitations that apply to emergency services from participating providers / emergency facility
  - (b) Not impose cost-sharing requirements that are greater than the requirements that would apply if the services were provided by a participating provider or participating emergency facility
  - (c) Calculate cost-sharing requirement as if total amount that would have been charged for services were equal to the "recognized amount"
  - Note: These terms are important but are a bit "in the weeds". For employers with self-funded group health plans, suggest that they require their vendors (e.g., TPAs) to follow these rules and the definitions, without the employer really getting into a specific level of detail

Surprise Medical Bills for Emergency Services

- If service is provided by a nonparticipating provider or a nonparticipating emergency facility, continued:
  - (d) Within 30 calendar days after a sufficient bill is received from the provider or facility (or such other timeframe specified by state law or All-Payer Model Agreement):
    - (i) Determine whether services are covered under plan and, if so, send to the provider or facility "an initial payment" or a "notice of denial of payment"
  - What is an "initial payment"? It is NOT a "first installment". It should be an amount the plan "reasonably intends to be payment in full" based on facts and circumstances
    - In essence, it's an amount the plan could pay to "head off" dispute process with provider

Surprise Medical Bills for Emergency Services

- If provider accepts "initial payment" (plus whatever cost-sharing amount enrollee paid) then these NSA protections do NOT apply (no "open negotiation period", no IDR process)
  - You (or your TPA / insurer / PBM) are done! (Also, in theory, provider could accept cost-sharing amount only, but that seems unlikely)
  - Agencies, in preamble, solicit input on whether they should establish a minimum amount as an initial payment (as some states do) (e.g., % of what Medicare pays)
- (e) Pays to nonparticipating provider / facility the amount by which the out-of-network rate for the services exceeds the enrollee's cost-sharing amount for the services, less initial payment
  - Within 30 days of IDR determination

Surprise Medical Bills for Emergency Services

- If service is provided by a nonparticipating provider or a nonparticipating emergency facility, continued:
  - (f) Count any cost-sharing payments made by the enrollee with respect to emergency services toward any in-network deductible or in-network out-of-pocket maximum ("MOOP"), as if services were done in-network

Surprise Medical Bills and HDHPs

- No formal examples of how rules work in the regulations. Preamble provides one:
  - Employee enrolled in self-only high-deductible health plan ("HDHP") with a $1,500 deductible. Employee has no other claims in the current plan year, then receives out-of-network emergency services. Plan determines that the "recognized amount" is $1,000. Employee must pay that amount. But provider wants $1,500 and that is determined to be appropriate. Plan must pay difference between out-of-pocket network rate and cost-sharing amount. So, plan pays $500. Employee's out-of-pocket amount limited to cost-sharing calculated under "recognized amount" (i.e., $1,000)
  - Plan's payment of $500 before deductible was satisfied would normally cause loss of HSA eligibility. But NSA modified Code Section 223 to prevent that

Non-Emergency Services by Nonparticipating Providers

- If the plan provides or covers non-emergency services to an enrollee at a participating health care facility, plan must cover certain items and services
  - Unless the provider has satisfied certain balance billing provisions
- (1) No cost-sharing that is greater than cost-sharing that would have applied if provider had been a participating provider

Non-Emergency Services by Nonparticipating Providers

- (2) Calculate cost-sharing requirements as if the total amount that would have been charged by provider were equal to the "recognized amount" for the items / services
- (3) Within 30 calendar days after bill is sufficient, pay provider the "initial payment" (or send notice of denial)

Non-Emergency Services by Nonparticipating Providers

- (4) Make total plan payment to nonparticipating provider equal to amount by which out-of-network rate for items / services exceeds cost-sharing amount for items / services, less the "initial payment" amount
- (5) Count cost-sharing payments made by enrollee toward in-network deductible / MOOP as if it were furnished by a participating provider

Air Ambulance Surprise Bills

- If a plan provides or covers any benefits for air ambulance services, must cover those services from a nonparticipating provider of air ambulance services
- (1) Cost-sharing must be same as would have applied if services were provided by a participating provider
- (2) Cost-sharing must be calculated as if total amount that would have been charged by a participating provider equaled the lesser of: (a) "qualifying payment amount" or (b) billed amount

Air Ambulance Surprise Bills

- (3) Cost-sharing amounts must be counted towards in-network deductible / MOOP in same manner as if in-network provider
- (4) Not later than 30 days after sufficient bill is received, determine if service is covered and if so send an "initial payment" (or denial notice if not covered)
- (5) Pay total plan payment made within 30 days of IDR determination date

"Qualifying Payment Amount" ("QPA")

- What must a plan pay for these services?
- "Specified state law" may set the rate IF it "applies"
- Agencies note that 14 states have set some payment standards for services provided by nonparticipating providers / NEFs
  - Commonwealth Fund lists 18 states with "comprehensive" protections; 15 with partial; 18 with no protection
    - See here: https://www.commonwealthfund.org/publications/maps-and-interactives/2021/feb/state-balance-billing-protections
- Agencies estimate 2/3 of all claims involving nonparticipating providers / NEFs will potentially need QPA calculation

QPA

- Basic idea: If All-Payer Model Agreement does not apply AND if state law does not apply to set what the plan must pay, then the plan (i.e., TPA on behalf of plan) AND provider / plan don't agree on payment, plan must pay the lesser of: (1) bill charged; or (2) QPA
- QPA is generally the "median of the contracted rates" recognized by the plan on January 31, 2019 for the same or similar items / services provided by a provider in the same or similar specialty and provided in a geographic region in which the item or service is furnished
  - 2019 date then adjusted for inflation

QPA Notices / Audits

- Regulations contain an unusual audit / enforcement provision
- IRS and DOL will "generally use existing processes" to ensure compliance with this regulation
- However, and apparently in addition, the regulations incorporate a separate HHS audit / complaint process
  - Random audits required
- Plan enrollees can complain, too
- Net takeaway for employers: Lots of moving pieces! Work with your vendors to make sure they are following them all

No Surprises Notice

- CAA modified Code Section 9820(c) and ERISA Section 720(c) to add a new notice requirement related to NSA
- New regulations, in the preamble, mention that the notice is required
  - E.g., must be sent with every EOB
- Model provided in separate document (not regulations):
  - https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/consolidated-appropriations-act/surprise-billing-model-notice.docx
- Agencies may issue more guidance in future

Patient Protections -- Updated

- ACA Section 2719A provided for various "patient protections" related to emergency services and the choice of health care professional
- Those will "sunset" when new CAA / NSA protections apply (i.e., plan years starting on or after January 1, 2022)
- Applies the rules to grandfathered health plans – noteworthy change for those plans
  - Verify self-funded employers following those terms in SPD
- Actual regulations re-published, only minor technical changes

Other CAA Obligations

- Other Consolidated Appropriations Act ("CAA") items – apparently will NOT be addressed in proposed or interim final regulations in 2021:
  - Insurance identification cards
  - Continuity of care
  - Accuracy of provider network directories
  - Prohibition on gag clauses
  - Pharmacy benefit and drug cost reporting (due December 27, 2021)
  - For "some" of these, rulemaking "might not occur until after January 1, 2022"

Other CAA Obligations

- In preamble to July 2021 regulations, agencies note that they intend to issue regulations "[l]ater this year" on:
  - Federal independent dispute resolution ("IDR") process
    - Formally published on October 7, 2021
  - Transparency and patient-provider dispute resolution process
  - Price comparison tools

New: Air Ambulance Reporting

- On September 16, 2021 the IRS, DOL and HHS issued proposed regulations on air ambulance reporting
- Group health plans and issuers must submit to, it seems, HHS (possibly DOL and IRS) certain information for calendar years 2022 and 2023
  - Due by 3/31/2023 and 3/30/2024
- Report must include detailed information about air ambulance services provided to plan enrollees
  - Discuss with TPA to verify if they will conduct reporting

New: IDR Process

- Regulations published October 7, 2021 contain detailed provisions on how IDR process works
  - Who can provide IDR services (e.g., cannot be your TPA or PBM or insurer)
  - Various administrative requirements of IDR entity (e.g., comply with HIPAA-like data privacy and security rules)
- Process generally applies when plan / provider cannot agree on acceptable price under other NSA rules
- Cost that IDR will charge is not clear, but in preamble agencies expect it might be $300 - $600 per claim (but note that some may cost thousands of dollars)

New: IDR Process

- Self-funded employers should make sure that:
  - Their vendors (e.g., TPAs) are going to set up a compliant process for these IDR rules (e.g., timely provide information to IDR entity)
  - Will TPAs take the lead in that process? Or put the burden back on employers? Presumably the former, but confirm
  - The cost for the process is discussed and documented (e.g., will TPAs pay the $300 - $600? Presumably not. Note that the provider pays if the provider "loses" in the IDR process)

New: External Review Clarifications

- October 7, 2021 regulations also clarify certain external review requirements
  - ACA required that non-grandfathered plans send certain decisions (usually those involving medical judgment) to a third-party, "external" reviewer for a binding determination after appeals process exhausted
- CAA expands types of claims eligible for external review
- Now includes "any adverse determination" by a plan under Code Sections 9816 or 9817

New: External Review Clarifications

- Code Sections 9816 / 9817:
  - (1) Benefits in an emergency department or independent freestanding emergency department
  - (2) Non-emergency services performed by nonparticipating providers in a participating facility
  - (3) Air ambulance bills
  - (4) Unclear if external review could apply to other provisions in Code Section 9816 (like "advanced explanation of benefits")
    - Those are probably not an "adverse determination"

New: External Review Clarifications

- New regulations contain some helpful examples
- E.g., suppose Employee receives pre-stabilization emergency services in an out-of-network emergency department of a hospital. Plan / TPA / insurer fails to apply special rules of Code Section 9816
  - In past, Employee likely could not have sought external review
  - Now, under new regulations, Employee can do so
- Takeaway for employers: Modify plan / SPD to reflect these additional rights of enrollees
  - Effective plan years starting 1/1/2022

ACA FAQ 49: Delays to New Legal Requirements

- Transparency regulations require public posting of: (1) in-network provider rates; (2) out-of-network allowed amounts and billed charges; and (3) prescription drug historical net prices
  - Now, #1 and #2 delayed to plan years starting July 1, 2022
  - Now, #3 delayed indefinitely due to regulations overlapping with CAA
- Prescription drug and other health care costs needed to be reported by December 27, 2021, then every June thereafter
  - Now, first report due December 27, 2022 (but it does seem to include 2020 and 2021 data)
- Price comparison tool (supposed to start January 1, 2022) now delayed until plan years starting in 2023
  - Tool allows enrollee to compare expected hospital costs, etc.

Important Delays to New Legal Requirements

- Advance explanation of benefits was effective January 1, 2022
  - Now, not enforced until agencies provide guidance (maybe in 2022? Guidance will not be issued in 2021)
- New ID card requirements; provider directory requirements; continuity of care requirements
  - No guidance coming soon; "good faith compliance" required until guidance actually is issued
- No contractual "gag clauses" prohibiting disclosures of cost and quality of care
  - No regulations coming soon, but compliance (except for a required report to federal government) is required (i.e., no delay; seems to be effective now)

Details on Other NSA Rules: Identification Cards

- Plan / issuer must include "in clear writing" on any physical or electronic plan or insurance identification card following information:
  - Deductible for the plan or coverage
  - Any MOOP
  - Telephone number and Internet website address for individual to seek consumer assistance information

NSA: Provider Discrimination

- ACA included a mysterious provision (Section 2706(a)) which prohibited discrimination against a provider "acting within the scope of that provider's license or certification under applicable state law"
- April 2013 FAQ stated that the provision was "self-implementing" and that IRS / DOL / HHS "do not expect to issue regulations in the near future" – which they stuck with (still no regulations or guidance on what it means)
- Maybe it means, e.g., that midwives who are licensed under state law cannot be discriminated against? That a plan cannot require that all births occur at a hospital (instead of at home with the help of a midwife)?
- No one really knows. But NSA states that HHS / DOL / IRS "shall issue a proposed rule" on it by 1/1/2022. Not clear when the rule will be finalized and effective

NSA: Continuing Care

- Effective for plan years starting 1/1/2022, if plan enrollee is receiving care at a health care provider or facility that "has a contractual relationship" with the plan (i.e., in-network) and enrollee is a "continuing care patient" and:
  - Contractual relationship between plan / issuer and provider terminates,
  - Benefits under the plan are terminated because of a change in the terms of the participation of the provider or facility in the plan, or
  - Contract between plan and issuer is terminating, resulting in loss of benefits provided under such plan for such provider or facility,
  - Then, special rules apply.
- Plan / issuer must notify enrollee of the termination and the enrollee's "right to elect continued transitional care" from the provider

NSA: Continuing Care cont.

- Allow enrollee to continue to have benefits provided under the plan, under same terms and conditions as would have applied if termination had not occurred, for that course of treatment.
- Enrollee must elect within 90 days of notice.
- "Continuing care patient" is enrollee:
  - Undergoing course of treatment for a serious and complex condition,
  - Undergoing institutional or inpatient care,
  - Scheduled to undergo nonelective surgery,
  - Pregnant and undergoing related course of treatment, or
  - Terminally ill.
- What if plan specifically excludes out-of-network coverage? Is this a mandatory exception to that rule?

NSA: Advanced EOBs

- For plan years starting 1/1/2022, a group health plan and health insurance issuer offering group or individual coverage must provide an "advanced explanation of benefits" ("Advanced EOB")
- Timing depends on when service is scheduled: 1 business day is standard, unless the item or service is scheduled at least 10 business days away, in which case 3 business days is the required time period
- Must include various information
- Whether provider or facility is a participating provider or facility
- If so, what the contracted rate under the plan is, based on the billing and diagnostic codes provided by the provider and facility

NSA: Advanced EOBs cont.

- If not participating, describe how such individual may obtain information of providers and facilities that are participating
- Good faith estimate of amount plan will pay, along with what enrollee will pay as cost-sharing
- Good faith estimate of enrollee's deductibles and MOOPs, as of date of notification
- If item or service is subject to "medical management techniques" (e.g., prior authorization, concurrent review, step-therapy or fail-first protocols), disclaimer that such techniques apply
- Disclaimer that information is only an estimate
- Other information plan determines to be appropriate

NSA: Price Comparison Tool

- Group health plans and health insurance issuers must offer "price comparison guidance" by telephone and on the Internet.
- Goal is, "to the extent practicable", to allow enrollee to compare cost-sharing that the individual must pay under the plan for a specific item or service for participating providers.
  - Does not seem to include out-of-network providers, which is a modest relief
- May raise concerns for TPAs, insurers and PBMs, as the rates negotiated with providers are often considered confidential and proprietary.
  - Can the rates on the Internet website be protected – e.g., enrollee must log into website, so rates are not-quite-so public? Could website terms limit the use of that information just for enrollee's benefit? (And do transparency regulations (later slides) make this moot?)
- Like many other changes here, plan sponsors will want to talk with vendors and make sure everyone knows who is doing what

NSA: Provider Directories

- Group health plans and insurance issuers must provide enhanced directories of health care providers.
  - Information related to provider is name, address, specialty, telephone number, digital contact information (email?) for in-network providers
- At least every 90 days, plan / issuer must verify and update provider directory information.
  - Remove providers and facilities if plan has been unable to verify such information
  - Update plan's database within 2 business days of receiving notice from the provider of "material changes" to the provider directory information
- When enrollee seeks this information, plan / issuer must respond "as soon as practicable", but always within 1 business day, in "written electronic or print" form, as requested by enrollee.
  - Also, retain that communication for at least 2 years

NSA: Provider Directories cont.

- Database on public website of plan / issuer must contain list of each health care provider and facility for which it has a "direct or indirect contractual relationship" and provider directory information.
  - Nitpicky question: For a typical employer, does the "group health plan" really have a website? Would that be the TPA's / PBM's website? Intranet site of employer?
- Written provider directory must state that information in the directory "was accurate as of the date of publication" and that enrollee "should consult the database" to "obtain the most current provider directory information."
- If plan / issuer incorrectly tells the enrollee that provider was in-network, or that item or service was in-network, then plan / issuer limited to what cost-sharing would have applied at the in-network level
  - Ouch! Large incentive to get this correct – will existing contract cover this if it is wrong?
  - Will TPAs, PBMs, insurers be able to "track" what the enrollee saw? Should they try? How? Keep record of every single iteration of the webpage?

NSA: No Gag Clauses

- Group health plans and insurance issuers cannot enter into an agreement with a health care provider, network or association of providers, TPA or other service provider offering access to a network of providers that would directly or indirectly restrict plan / issuer from offering certain information
- Provider-specific cost or quality-of-care information or data, through a consumer engagement tool or any other means, to referring providers, plan sponsor, enrollees or individuals eligible to become enrollees
  - Does not seem to include general public

NSA: No Gag Clauses cont.

- Electronically accessing de-identified claims and encounter information or data for each enrollee in the plan or coverage, upon request and consistent with HIPAA Privacy Rule, GINA and ADA, including on a per claim basis:
  - Financial information, such as allowed amount, or any other claim-related financial obligations included in the provider contract,
  - Provider information, including name and clinical designation,
  - Service codes, or
  - Any other data element included in claim or encounter transactions.
- Sharing information or data and directing that such information be shared with a business associate
  - Appears to make it a lot easier for a plan sponsor to obtain claims information from, e.g., TPA and share that with a consultant (e.g., insurance broker) to have the consultant analyze the data

NSA: No Gag Clause cont.

- Plans / issuers must annually submit to the Secretary an "attestation" that they are "in compliance" with these requirements
- No specified effective date – seems it is currently effective
  - Is there an argument that it only applies to new contracts entered into after the CAA's effective date? What about renewals of those contracts?
- Presumably will, at some point, require many TPA / PBM contracts to be updated
  - And issuers, TPAs, PBMs may need to update contracts with providers (which may contain this type of clause too)
  - Could a "we comply with all applicable laws" sentence in a contract suffice?
- The Alliance has taken action in this area already

NSA: Compensation Disclosures

- Group health plans must disclose, for "brokerage services" and "consulting" services, certain information
- Only applies if the service provider reasonably expects to receive $1,000 or more in direct or indirect compensation in connection with its services
- Various information must be in the disclosure
- Services to be provided
- If applicable, a statement that service provider will provide services as a fiduciary
- Describe all direct compensation that is reasonably expected

NSA: Compensation Disclosures cont.

- Describe all indirect compensation that is reasonably expected and what services relate to that indirect compensation
- Describe arrangement between payer and the service provider
- Describe compensation that will be paid among the service provider, affiliate or subcontractor, if compensation is "set on a transaction basis" (like a commission or finder's fee)
- Manner in which compensation will be received
- Service provider must disclose information in advance of date of contract or renewal of contract
- If any change to compensation, service provider must disclose as soon as practicable, not later than 60 days from date on which service provider is informed of such change, unless "extraordinary circumstances" prevent that

NSA: Compensation Disclosures cont.

- If service provider makes an error, must correct it within 30 days
- If plan sponsor / fiduciary becomes aware of service provider's failure, it must "request[] in writing that the covered service provider furnish such information."
  - If service provider refuses, notify the Secretary (within 30 or 90 days, depending on the situation)
- If service provide refuses to provide information, plan fiduciary "shall terminate the contract ... as expeditiously as possible, consistent with such duty of prudence"
- Only applies to brokerage or consulting services; probably not to PBMs or TPAs
- Does it only apply if ERISA plan assets are involved?
  - New proposed regulations from 9/16/2021 do not address this
- Probably no contracts have these terms in place now; need to update them

NSA: Compensation Disclosures

- September 16, 2021 proposed regulations from HHS provided some guidance
  - Technically only for health insurance issuers offering individual coverage or short-term, limited-duration insurance
  - So, these rules do NOT apply to group health plans
  - BUT, will DOL and IRS adopt HHS rules? In part? Entirely? Use, e.g., their definitions as a "guide"?
    - Presumably there will be overlap, so reviewing those definitions may help us predict future

NSA: MHPAEA Analysis

- Group health plans / insurers that provide mental health or substance use disorder benefits ("MH/SUD") must comply with Mental Health Parity and Addiction Equity Act ("MHPAEA")
- One requirement is that nonquantitative treatment limitations ("NQTLs") cannot, in general, apply more stringently to MH/SUD benefits compared to medical / surgical ("M/S") benefits
- Starting February 10, 2021, federal government can ask for a written "comparative analysis" of how NQTLs apply to those different types of benefits
  - And DOL HAS been asking for that, and only providing about 5 - 10 calendar days to respond to a "narrow" piece (and a couple weeks more to respond to a "broad" piece)

NSA: MHPAEA Analysis cont.

- "Specific plan or coverage terms" and a description of "all" MH/SUD benefits to which each such term applies in each "respective benefits classification"
- Factors used to determine that the NQTLs will apply to MH/SUD and M/S benefits
- Evidentiary standards used for those factors
  - Every factor "shall be defined" – what does that mean?
  - Any source or evidence relied upon to design and apply the NQTLs to MH/SUD and M/S benefits
    - This is information that a TPA, PBM or insurer would probably know, but a plan sponsor would not. Will require discussions among the parties. Also not information that, in our experience, TPAs have typically provided to plan sponsors (very "in the weeds" and some would argue is proprietary)

NSA: MHPAEA Analysis cont.

- Comparative analysis demonstrating that processes, strategies, evidentiary standards and other factors used to apply NQTLs, "as written and in operation" are not applied more stringently
  - The "and in operation" piece may be difficult because, almost by definition, it involves procedures which are not written (so plan sponsor cannot just ask for the plan, SPD, written policies, etc. – may need to go "beyond the documents")
- "Specific findings and conclusions" reached by the plan / issuer "including any results of the analyses ... that indicate that the plan or coverage is not in compliance with this section"
  - In essence, "confess your sins" if asked to do so
  - Is it possible to shield that through attorney-client privilege?
- Must provide to Secretary, enrollee, state regulator upon request
  - If Secretary thinks it is insufficient, must respond to Secretary

NSA: Drug Price Reporting

- By 12/27/2021 (original effective date, now delayed) then as of each June 1 thereafter, plan / issuer must submit certain information to HHS, DOL and IRS
- Beginning and end dates of plan year
- Number of enrollees
- Each state in which the plan or coverage is offered
  - Will this require an enrollee-by-enrollee determination? What about COBRA enrollees who, say, move to another state? What about children away at college?
- 50 brand prescription drugs most frequently dispensed by pharmacies for claims paid by the plan and total number of paid claims for each such drug
- 50 most costly prescription drugs by total annual spending and annual amount spent by plan for each such drug

NSA: Drug Price Reporting cont.

- 50 prescription drugs with greatest increase in plan expenditures over the plan year preceding plan year of report
  - And, for each drug, change in amounts expended by plan or coverage
- Total spending on health care services by plan / issuer
  - Broken down by type of costs, including hospital costs; provider and clinical service costs, for primary and specialty care; prescription drug costs; other medical costs "including wellness services"
  - Average monthly premium paid by employers and enrollees
- Impact on premiums by rebates, fees and other remuneration paid by drug manufacturers
  - Amount paid for each therapeutic class of drugs and amounts paid for each of the 25 drugs that yielded highest amount of rebates and other remuneration from drug manufacturers
- Secretary will put together report (non-identifiable to a plan) within 18 months

Transparency Regulations

- Regulations published November 12, 2020 impose new "transparency" rules
  - Does the CAA overlap with these? Seems to. Perhaps because some of the CAA transparency rules were "copied and pasted" from a prior bill, without, it seems, much time spent trying to harmonize those CAA rules with these regulations
- Applies to self-funded group health plans and, unusually, fully-insured plans
  - "Safe harbor" for sponsors of fully-insured plans if issuer agrees in writing to comply
    - Issuers and employers should discuss this
  - Likely applies to non-grandfathered health plans, but not retiree-only plans or excepted benefit plans
- Goals of having providers compete more on price and improving information of plan enrollees (to make cost-conscious decisions)
- Effective for plan years starting 1/1/2022, public posting, in machine-readable files, of three types of information (now delayed)

Transparency Regulations cont.

- In-network file: All negotiated rates and fee schedules with in-network providers
- Out-of-network: Information on historical allowed amounts for covered items and services
- Prescription drug: Negotiated rates and historical net prices for prescription drugs with respect to in-network providers
  - Having all three be publicly available is extremely significant. Allows more comparison based on cost. But will data be less valuable without some way to compare quality or complexity? Will employers build in incentives for employees to go to certain hospitals for certain procedures (e.g., go to Hospital ABC and you will receive a $300 HSA contribution; go Hospital DEF and receive nothing)?
- Update files monthly

Transparency Regulations cont.

- For plan years starting 1/1/2023, disclose estimates of cost-sharing to an enrollee and 500 specified items and services
  - Goal is to provide it ahead of services – seems similar to CAA's "advanced EOB" rule
  - For plan years starting 1/1/2024, all covered items and services
- Must be through online tool and in paper, for current enrollees
- Tool should be specific to particular in-network providers or all in-network providers
- Tool should take into account different cost-sharing based on multi-tier networks and particular care settings (e.g., in-patient; outpatient; in a hospital; out of network)
- If bundled payment, need only include those with separate costs

Transparency Regulations cont.

- If it could be "preventive" but plan / issuer is not sure, provide the cost-sharing
- Accumulated amounts
- In-network rate, including:
  - Negotiated rate, reflected as a dollar amount, for the requested item or service
  - Underlying fee schedule rate, reflected as a dollar amount
- Out-of-network allowed amount "or any other rate that provides a more accurate estimate" of what the plan / issuer will pay
- If enrollee asks for an item or service subject to a bundled payment arrangement, list of items / services in the bundle

Transparency Regulations cont.

- Statement to enrollee that out-of-network provider may balance bill (if balance billing allowed in the state)
  - And that it's only an estimate
  - Whether copayment assistance or other third-party payments in deductible / MOOP
- Preventive at no charge; other relevant statements
- "Good faith" exceptions to penalties if act with reasonable diligence
- Error / omission made (correct as soon as practicable)
- Website is temporarily not accessible
- If need information from another entity, ok unless knew or should have known information was inaccurate or incomplete

"Grab Bag" of New Guidance

- Sometimes TPAs, PBMs and insurers will record phone calls made by enrollees, or create a transcript of them
- ERISA provides that enrollees may receive copies of "all documents, records, and other information relevant to the claimant's claim for benefits"
- Does that include copies of the phone calls and transcripts?
- New DOL opinion letter says "yes"

COBRA "Clarifications"

- On October 6, 2021, the IRS "clarified" (read: significantly and unexpectedly modified) prior guidance about COBRA and the COVID delayed time periods
  - Per IRS Notice 2021-58
- Prior guidance strongly indicated that each action was treated individually and each received own 1-year delay
  - E.g., employee terminated on October 1, 2020. Employee would have 60 days + 1 year to elect COBRA. Then 45 days + 1 year to pay for first month's COBRA. So, initial payment could be years after termination of employment

COBRA "Clarifications"

- New rules:
  - If individual elected COBRA outside initial 60-day COBRA election timeframe, generally will have one year and 105 days after the date the COBRA notice was provided to make the initial COBRA payment
  - If individual elected COBRA within initial 60-day timeframe, he / she has one year and 45 days after the date of the COBRA election to make the initial COBRA payment

COBRA "Clarifications"

- Because this is essentially a new rule, transition relief provides that in no event will initial COBRA premium payment be due before November 1, 2021, as long as individual makes initial COBRA premium payment within one year and 45 days after election date
- Future premium payments due one year from date payment would originally have been made
- IRS Notice 2021-58 provides 10 different, detailed examples – employers should review them

COBRA "Clarifications"

- Example 2: Kate participates in Employer Y's plan. Kate has a qualifying event and receives a COBRA election notice on October 1, 2020. Kate elects COBRA on October 15, 2020, retroactive to October 1, 2020. By when must Kate make her initial and ongoing COBRA premium payments?
- Kate has until November 29, 2021 to make the initial payment (i.e., one year and 45 days after when she elected COBRA, on October 15, 2020). That rule would be different if Kate had elected outside the "regular" 60-day time period, but she did not

COBRA "Clarifications"

- Initial payment Kate makes will pay for October 2020
- November 2020 payment is due by December 1, 2021 (one year and 30 days after November 1, 2020). Premium payments due every month after that for months Kate is eligible
- Kate's COBRA should end on March 30, 2022
  - But, her last payment for March 2022 will be due on October 31, 2022
  - Will Kate really keep paying so many months after COBRA ended?
- Employers should double-check prior communications on COBRA and COVID. They likely did NOT interpret the guidance this way
- If so, should send out a notice, quickly, to tell qualified beneficiaries

Continuing Saga of ACA Section 1557

- Prohibits covered entities which receive federal financial assistance from discriminating "on the basis of sex"
- Obama administration said it applied to LGBTQ status
- Required gender reassignment coverage in health plan
- Trump administration cut back on that interpretation
- May 2021: Biden administration applies it broadly
- Still lot of litigation over its breadth
  - EEOC also active in this area and continuing to make claims

EBSA Cybersecurity "Best Practices"

- In April 2021, EBSA issued a "best practices" document for plans that hold "assets and "maintain personal data on participants"
  - "Responsible plan fiduciaries have an obligation to ensure proper mitigation of cybersecurity risks"
- Twelve things that plans' service providers should do, including:
  - Have a formal, well document cybersecurity program
  - Conduct "prudent" annual risk assessments
  - Have a reliable annual third party audit of security controls
- Some go beyond HIPAA. So, while focus is on retirement plans (and the risk is bigger there), also consider whether to update business associate agreements

HIPAA Changes

- On January 5, 2021, President Trump signed into law the HIPAA Safe Harbor Bill
- HHS will take into account covered entity's or business associate's use or certain industry standards (e.g., NIST) "developed, recognized, or promulgated through regulations under other statutory authorities"
  - Should plans / sponsors / TPAs / PBMs identify the "weakest" such authority and make sure they follow it?
- Some standards (e.g., NIST) may be very onerous, especially for employers, who typically hold little PHI
- Discuss with plan sponsor's IT department
  - Possibly update written HIPAA Security Rule policies and procedures to incorporate as many of those standards as possible
- On a different topic, 5th Circuit held that HHS's penalty against Texas medical provider not allowed under HIPAA
  - Seems like a good defense if you face a HIPAA breach and large HHS penalty

Questions?

Thank You

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Questions

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Thank You

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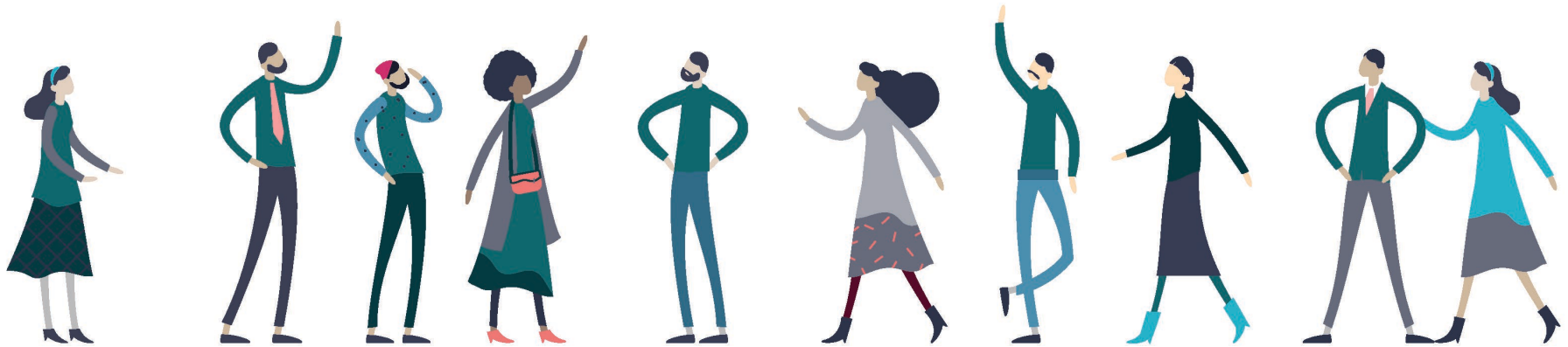

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