2021 Prescription Carve Out Plans Compliance Checklist

Health Action Council

Last updated as of April 27, 2021

| Issue | Background | Recommended Action Items | Status |
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| COVID-19 – Group Health Plan Cover | age Mandates and Permitted Coverage | | |
| Required coverage of COVID | Description: | Implementation: | |
| Required coverage of COVID Vaccine Source(s): Coronavirus Aid, Relief, and Economic Security ("CARES") Act (2020) Interim Final Rule FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Part 44 Interim Final Rule: Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; 85 Fed. Reg. 71142 (Nov. 6, 2020). | Description: During the HHS-declared COVID-19 public health emergency, non-excepted benefit, non-grandfathered group health plans (e.g., medical/Rx plans) must: Provide expedited full coverage of approved COVID vaccines (must cover the cost of the vaccine and administration costs within 15 business days after either the U.S. Preventive Services Task Force (USPSTF) makes a recommendation to treat the vaccine as preventive care or the director of the Centers for Disease Control and Prevention adopts a recommendation by the Advisory Committee on Immunization Practices (ACIP) to treat the vaccine as preventive care) Cover the vaccine and its administration cost as preventive care whether received from an in-network provider or an out-of-network provider during the COVID-19 public health emergency Applies to fully insured and self-insured group health plans, including grandfathered group health plans. Does not apply to HIPAA excepted benefits (e.g., stand-along dental and vision, health care FSA, etc.) and retiree-only plans. After the end of the public health emergency, the standard preventive care rules will apply – e.g., Standard timeline (one year) for coverage of newly recommended preventive care Coverage without cost-sharing required only for innetwork providers | Ensure insurers and third-party administrators are prepared to: Cover recommended vaccines and administration costs as preventive care within the 15-business-day deadline. Provide full coverage whether received from an innetwork provider or an out-of-network provider during the COVID-19 public health emergency. Sponsors of grandfathered plans should consider what if any impact voluntarily expanding coverage for COVID vaccines will have on the plan's grandfathered status. <u>Plan Amendments</u>: Determine whether plan amendments are needed. Ensure that 2021 certificates of coverage/benefit booklets either specifically address the mandated coverage or include a | |

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| | age Mandates and Permitted Coverage <u>Description</u> : The CARES Act and related IRS guidance includes relief allowing group health plans that are HDHPs greater flexibility to expand coverage (e.g., for telemedicine) and waive cost-sharing without impacting HSA eligibility. | Plan Amendments: Determine whether plan amendments are needed to address any coverage changes implemented during 2020 and/or 2021 related to COVID-19. Ensure that applicable certificates of coverage/benefit booklets either specifically address the coverage changes or include a disclaimer that they do not override previous communications/SMMs related to temporary coverage changes required in connection with COVID-19. Employee Communications: Consider whether expanded coverage has been adequately communicated to employees. A follow up communication may be needed when the plan reverts back to standard coverage provisions. Plans must ensure notice is provided sufficiently in advance of reducing | Status |
| HIPAA Special Enrollment, COBRA, and ERISA Claims/Appeals Deadline Extensions Source(s): Final Rule: Extension of Certain Timeframes for Employee Benefit Plans, Participants, and Beneficiaries Affected by the COVID-19 Outbreak, 29 CFR Parts 2560 and 2590; 26 CFR Part 54, 85 Fed. Reg. 26351 (May 4, 2020) COVID-19 FAQs for Participants and Beneficiaries (Apr. 28, 2020) EBSA Disaster Relief Notice 2021-01, Guidance on Continuation of Relief for Employee Benefit Plans and Plan Participants and Beneficiaries Due to | <u>Description</u> : The following deadlines are tolled for a period not to exceed one year during the "Outbreak Period" (i.e., the period beginning March 1, 2020 and ending 60 days after the announced end of the COVID-19 national emergency): (i) HIPAA special enrollment requests, (ii) certain COBRA notifications, (iii) COBRA election and payment periods, (iv) submitting claims, appeal requests, external review requests, and additional information required for an external review. | <u>Implementation</u>: Coordinate with TPAs/insurers to ensure that the deadline extensions are appropriately administered. Determine whether any plan changes or amendments should be adopted as part of the response to this guidance. Consider whether any changes to COBRA administration are needed (e.g., to pend coverage during periods of nonpayment). If providing broader relief that what is required by law (e.g., not counting days that elapsed prior to the start of the Outbreak Period; applying special enrollment extensions to excepted benefit dental and vision benefits, etc.), ensure any insurers and/or stop loss carriers agree to the extensions. Consider gaps in stop loss coverage related to aging claims/appeals. <u>Plan Amendments</u>: Determine whether plan amendments are needed. | |

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| HIPAA Special Enrollment, COBRA, and ERISA Claims/Appeals Deadline Extensions cont the COVID-19 (Novel Coronavirus) Outbreak | | Ensure that 2021 SPDs/benefit booklets include a description of the deadline extensions or a disclaimer that they do not override previous communications/SMMs related to temporary relief provided in connection with COVID-19. <u>Employee Communications</u>: Provide appropriate notice of the changes to active employees and others impacted by the extensions. | |
| ARPA COBRA Subsidies | Description: | Recommended Action Items: | |
| Source(s): American Rescue Plan Act of 2021, Pub. L. No. 117-2 (2021) DOL FAQs and model notices, available at: https://www.dol.gov/agencies/ebsa/l aws-and- regulations/laws/cobra/premium- subsidy | ARPA creates a full premium subsidy (covering 100% of qualified beneficiaries required contribution) for COBRA coverage for employees/dependents who: (a) lose/lost group health plan coverage due to an involuntary termination of employment or on account of a reduction of hours, and (b) who are not eligible for any other group health plan or Medicare coverage. The premium subsidy applies for any period of coverage during the period beginning April 1, 2021 and ending September 30, 2021. Plans subject to federal COBRA must give the following subsidy-eligible individuals ("Second Chance Individuals") a new opportunity to elect COBRA: (1) any individual who did not elect COBRA continuation coverage but otherwise would have been eligible for the COBRA subsidy and (2) any individual who elected COBRA continuation coverage and discontinued such coverage before the subsidy period began. Plans are required to modify current COBRA notices to address the subsidy, provide notices to individuals qualifying for a second enrollment opportunity and notify participants when the subsidy is ending. The DOL issued model notices. Plans may, but are not required, to give subsidy-eligible individuals the option to switch to a lower-cost coverage option. | Identify former employees who lost coverage due to an involuntary termination of employment or reduction in hours. Identify the applicable termination codes. Consider how far to look back. The DOL model notices and election forms do not ask qualified beneficiaries to specify when they would like coverage to begin (April 1, 2021; prospectively from the date of election; or earlier if eligible). Consider how the Plan/COBRA Administrator will determine the desired start date. The DOL model notices do not address domestic partner coverage (in general, domestic partners are not COBRA qualified beneficiaries and therefore are not subsidy eligible). Consider how domestic partner coverage issues and premium payments will be addressed. Coordinate with COBRA vendor regarding notices and implementation of subsidy assistance. Prepare for receipt of Requests for Treatment as an Assistance Eligible Individual Forms that participants may submit independently and before receipt of updated notices. Consider whether to allow assistance-eligible individuals to switch into a lower-premium plan option. Consider whether to amend severance programs and/or revise severance agreements to reduce or eliminate company-provided subsidies. Consider potential impact on claims experience. | |

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| ARPA COBRA Subsidies cont | In most cases, employers are required to cover the premium costs for subsidy-eligible individuals and then seek reimbursement from the federal government in the form of a refundable payroll tax credit. Subsidy applies to all group health plans (e.g., medical, dental, vision, EAP) except healthcare FSAs, and is available for federal COBRA and state mini-COBRA | <u>Required Notices</u> Notice to subsidy-eligible individuals who became entitled to elect COBRA prior to April 1, 2021 Notice must be provided by May 31, 2021 Applies to subsidy-eligible individuals currently enrolled in COBRA and Second Chance Individuals Modified COBRA election notice for qualified beneficiaries who become entitled to elect COBRA during the subsidy period General timing rules apply (COVID-19 deadline extensions do not apply) Notice to persons whose subsidy will expire for reasons other than eligibility for other group health plan coverage or Medicare Must be provided at least 15 days but no more than 45 days prior to the end of the subsidy | |
| Group Health Plan Price Transparency Final Rule – Public Disclosures Source(s): Final Rule: Transparency in Coverage, 26 CFR Part 54; 29 CFR Part 2590; 45 CFR Parts 147 and 158, 85 Fed. Reg. 72158 (Nov. 12, 2020). | <u>Description</u>: Effective for plan years beginning on or after January 1, 2022, covered plans/insurance issuers must make publicly available the following three machine readable files (i.e., digital files that can be used for further processing of data): File 1 → Payment rates negotiated between plans or issuers and in-network providers. File 2 → Historical pricing information showing unique allowed amounts and billed charges for covered items and services furnished by out-of-network providers. File 3 → Information on prescription drug pricing (the in-network negotiated rates and historical net prices for all covered prescription drugs by plan or issuer at the pharmacy location level). The files must include detailed pricing information for all covered items and services, including encounters, procedures, medical tests, supplies, durable medical | Contact TPAs/insurers to determine whether and to what extent they can provide and regularly update the required disclosures. New contracts and amendments to current contracts should specify who will be responsible for developing and updating the required digital files. If you are preparing to undergo an RFP or renegotiate a third party administrator ("TPA") contract or insurance contract in the next year, ensure that your RFP and/or new contract addresses the disclosure requirements. If your current contract will not be up for renewal in the next year, reach out to your insurer or TPA to discuss amending your contract to address the disclosure requirements. If your plan has a pharmacy benefit carve-out, also contact your pharmacy benefit manager and/or specialty drug administrator. | |

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| Group Health Plan Price Transparency Final Rule – Public Disclosures cont | equipment, prescription drugs, and fees (including facility fees). Plans cannot charge a fee to access the files or require individuals to establish a user account or submit any personally identifiable information to access the files. The files must be updated monthly and reflect the date of the most recent update. | • Plan Sponsors should anticipate increased plan administration costs/fees related to the new reporting requirements when budgeting for the 2022 plan year. | |
| | Applies to both self-insured and fully-insured medical and prescription drug plans. Does <u>not</u> apply to grandfathered health plans, retiree-only plans, excepted benefits (such as limited-scope dental and vision benefits), or certain other arrangements that are exempted from the Affordable Care Act's market reform provisions. | | |
| | <u>Responsibility for Noncompliance</u>: Where fully-insured plans contract with the insurer or other third party (such as a health care clearinghouse) to provide the required information, the insurer or third party will be responsible for any noncompliance. Self-insured plan sponsors will remain responsible for compliance (and any non-compliance) even if they contract with third parties to provide the required disclosures. | | |
| Group Health Plan Price Transparency Final Rule – Participant Disclosures Source(s): Final Rule: Transparency in Coverage, 26 CFR Part 54; 29 CFR Part 2590; 45 CFR Parts 147 and 158, 85 Fed. Reg. 72158 (Nov. 12, 2020). | <u>Description</u>: Effective for plan years beginning on or after January 1, 2023, covered plans must make available to participants, beneficiaries, and enrollees (or their authorized representatives) personalized out-of-pocket cost-sharing information and underlying negotiated rates for covered healthcare items and services. <i>Format</i>: Information must be provided through an internet-based self-service tool and, upon request, in paper form. <i>Information required to be disclosed</i>: Includes estimated cost-sharing liability, amounts already | Contact TPAs/insurers to determine whether and to what extent they can provide and regularly update the required disclosures. New contracts and amendments to current contracts should specify who will be responsible for developing, hosting, maintaining, and updating the required databases and who will be responsible for responding to requests for paper disclosures. If you are preparing to undergo an RFP or renegotiate a third party administrator ("TPA") contract or insurance contract in the next year, ensure that your RFP and/or new contract addresses the disclosure requirements. | |

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| CAA Transparency Requirement – TPA Gag Clause Prohibition <u>Source(s)</u> : Consolidated Appropriations Act ("CAA"), 2021, Pub. L. 116-260, 134 Stat. 1182 (Dec. 27, 2020) | Description: Effective as of the enactment of the CAA (December 27, 2020), group health plans cannot enter into agreements that directly or indirectly restrict the plan from: Disclosing provider-specific cost or quality-of-care information or data through a consumer-engagement tool or other means, to referring providers, the plan sponsor, enrollees, or individuals eligible to become enrollees; Electronically accessing de-identified claims information (in accordance with HIPAA, GINA and the ADEA); or Sharing this information with a business associate. Group health plans and health insurance issuers will be required to submit an annual attestation that the plan or insurer is in compliance. The method of reporting has not been addressed and further guidance is needed. | Review current contracts to flag impermissible gag clauses and request amendments as needed. Additional federal guidance is expected on the reporting requirement. | |
| CAA Transparency Requirement – Broker/Consultant Compensation Disclosures <u>Source(s)</u> : Consolidated Appropriations Act ("CAA"), 2021, Pub. L. 116-260, 134 Stat. 1182 (Dec. 27, 2020) | <u>Description</u>: The CAA expands ERISA Section 408(b)(2) service provider compensation disclosure rules to apply to group health plans Effective December 27, 2021, prior to entering into, extending or renewing a contract with a group health plan, certain brokers and consultants must provide the plan with a description of the services to be provided and the type of compensation that the broker/consultant reasonably expects to receive. | • Plan sponsors should be aware of these requirements when negotiating new contracts or renewals with brokers and consultants, and should request Section 408(b)(2) disclosures if none are provided. | |
| CAA Transparency Requirement – MHPAEA Nonquantitative Treatment Limitation ("NQTL") Analyses and Reporting | <u>Description</u>: The CAA builds upon the Mental Health Parity and Addition Equity Act (MHPAEA) by requiring plan sponsors and insurers to provide, upon request of the DOL, HHS, or other regulatory agency, written comparative analysis of NQTLs. | Recommended action items: Plan Sponsors should work with their insurers and TPAs to identify the NQTL applicable to mental health and substance use disorder benefits, specifically pharmacy benefits, especially if provided via a separate TPA/PBM. | |

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| COVID-19 – Group Health Plan Cover <u>Source(s)</u>: Consolidated Appropriations Act ("CAA"), 2021, Pub. L. 116-260, 134 Stat. 1182 (Dec. 27, 2020) FAQs About Mental Health and Substance Use Disorder Parity Implementation and the Consolidated Appropriations Act, 2021 Part 45 (April 2, 2021) DOL Guidance, available at https://www.dol.gov/agencies/ebsa/l aws-and-regulations/laws/mental- health-and-substance-use-disorder- parity | age Mandates and Permitted Coverage Pursuant to the new requirements: Each year, group health plans/insurers must complete and document comparative analyses of the design and application of NQTLs imposed on mental health and substance use disorder (MH/SUD) benefits. As of February 10, 2021, plans and insurers must be prepared to provide copies of those analyses and related information to applicable state or federal agencies (e.g., DOL, HHS) upon request. The information that must be provided (if requested) includes: The specific plan or coverage terms or other relevant terms regarding the NQTLs and a description of all MH/SUD and medical or surgical benefits to which each such term applies in each respective benefits classification; The factors used to determine that the NQTLs will apply to MH/SUD benefits and medical or surgical benefits; The evidentiary standards used for those factors and any other source or evidence relied upon to design and apply the NQTLs; The comparative analyses demonstrating that (a) the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or more stringently than, (b) the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in each benefits classification; and | Determine what resources your insurers/TPAs are willing to provide: E.g., Are they able to at least provide any analysis they've conducted regarding NQTLs that are standard across the TPA's book of business and/or for fully-insured plans. Document analyses based on the information provided by your TPAs/insurers using the DOL's self-compliance tool. Consider addressing MHPAEA in a more robust, detailed manner in future TPA contracts. | |

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| COVID-19 – Group Health Plan Cover CAA Transparency Requirement – Reporting of Pharmacy Benefits and Drug Costs Source(s): Consolidated Appropriations Act ("CAA"), 2021, Pub. L. 116-260, 134 Stat. 1182 (Dec. 27, 2020) | age Mandates and Permitted Coverage <u>Description</u>: The CAA requires group health plans to report the following pharmacy and drug information on an annual basis: The plan year, number of participants and beneficiaries and each state in which the coverage is offered; The 50 most frequently dispensed brand name prescription drugs and the total number of paid claims for each such drug; The 50 most expensive drugs covered by the plan and the annual amount spent by the plan for coverage of such drugs; The 50 prescription drugs with the greatest increase in plan expenditures over the preceding year and the change in the amounts expended by the plan for each drug; Total spending by the plan on health care services, broken down into certain categories including hospital costs, health care provider and clinical service costs for primary and specialty care, costs for prescription drugs and other medical costs including wellness services and amounts spent on prescription drugs by the plan and participants; The average monthly premium paid by the employer (on behalf of participants) and by participants; The first report must be made to the Secretaries of Labor, Health and Human Services ("HHS") and the Treasury no later than December 27, 2021. Subsequent reports must be provided on an annual basis no later than June 1. Additional guidance on the manner of the required reporting is needed. | Note that this may require information from multiple vendors (e.g., medical TPA, PBM, etc.) Contact TPAs/insurers to determine whether and to what extent they can: Submit the reporting on behalf of the plan; or Provide the information necessary for the plan to submit the required reporting. New contracts and amendments to current contracts should specify who will be responsible for this reporting requirement. | |

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| CAA No Surprises Act – Disclosure/ Transparency Requirements Source(s): Consolidated Appropriations Act ("CAA"), 2021, Pub. L. 116-260, 134 Stat. 1182 (Dec. 27, 2020) | Description: The No Surprises Act imposes several transparency requirements on group health plans, effective as of January 1, 2022, including but not limited to: A requirement to include certain information on insurance identification cards. A requirement for group health plans to provide an advanced explanation of benefits ("advanced EOB") to participants prior to scheduled care or upon request prior to scheduling. A requirement for group health plans to maintain a price comparison tool online allowing a participant to compare his or her cost-sharing obligations for a particular service among multiple providers. The same information must also be available by phone. A requirement for group health plans to establish and monitor accurate provider directories for in-network providers, and to verify and update the directories at least every 90 days and within two days after notification of a change from a provider. A requirement that plans respond to an inquiry by a participant as to the network status of a provider within one business day of the inquiry. | Plan sponsors should contact service providers to ensure the new administrative requirements related to the CAA are timely completed and determine which parties will be responsible each of the required disclosures. | |

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| | Background rage Mandates and Permitted Coverage Description: The No Surprises Act also established a scheme to prevent plan participants from being balance billed for certain out-of-network services. Effective January 1, 2022: Out-of-network providers of air ambulance services and out-of-network providers of air ambulance services are prohibited from billing insured patients beyond the cost-sharing requirement that would apply if the services were provided in-network. If an insured patient does not give prior consent (following the provision of advance notice meeting certain notice requirements), out-of-network providers of non-emergency services at in-network facilities are prohibited from billing insured patients beyond the cost-sharing requirement that would apply if the services were provided in-network. Automatically subjects certain "ancillary services" (which include, but are not limited to, services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology, and items and services provided by assistant surgeons, hospitals, and intensivists) to the balance billing the participant, group health plans are also prohibited from subjecting participants to cost-sharing requirement and the rate of reimbursement for the provider. Requires group health plans and out-of-network k providers to engage in an Independent Dispute Resolution ("IDR") process to negotiate and ultimately | <u>Fully Insured Plans</u> The insurer will ultimately be responsible for determining payment of claims under the Act and ensuring compliance. <u>Self-Insured Plans</u> To the extent claims processing authority has been delegated to TPAs, the initial payments, decisions to initiate the IDR process, and ultimate results of the IDR process will likely be made by the TPA. Plan sponsors with self-insured medical plans should start discussions with their TPAs about their proposed processes for addressing claims under the Act consider engaging in contract negotiations with their TPAs surrounding this issue. Plan sponsors should also consider that this may have the effect of increasing plan expenses, both due to increased fees charged by TPAs and increased claims payments. | |