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Transparency Provisions of the Consolidated Appropriations Act, 2021 and More

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Agenda

- Machine-readable file requirements
- No Surprises Act
- NQTL Comparative Analysis
- Michigan Nonopioid Directive Form
- Coverage of ASD Benefits
- Questions

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Transparency in Coverage ("TiC") Regulations: Machine-Readable Files

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Machine-Readable Files

- For plan years beginning on or after January 1, 2022, the TiC regulations require non-grandfathered group health plans to disclose the following information in three separate machine-readable files on a public website:
  - In-network provider rates for covered items and services
  - Out-of-network allowed amounts and billed charges for covered items and services
  - Negotiated rates and historical net prices for covered prescription drugs

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Machine-Readable Files

- Delayed effective dates:
  - The DOL, IRS and HHS delayed the effective date of the machine-readable file requirement:
    - Until July 1, 2022 for in-network provider rates and out-of-network allowed and billed amounts (but plans that are subject to this requirement before July 1 will still need to publish this information for January 1 – June 30)
    - Until further regulations are issued for prescription drug information

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Machine-Readable Files

- The information must be a digital representation of the data in a file that can be imported or read by a computer system for further processing without human intervention (e.g., JSON, XML, CSV) (See DOL FAQs on ACA Implementation Part 53)
- By "public website" the TiC regulations require the machine-readable files to be posted to a website that is:
  - Accessible free of charge
  - Does not require a user account, password, or other credentials
  - Does not require the user to submit any personal information (e.g., name or email address)

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Machine-Readable Files

- Non-duplication
  - If a plan sponsor of a fully insured plan enters into a written agreement with the insurer under which the insurer will publically publish the machine-readable files and the insurer fails to do so, it is the insurer, not the plan (or the plan sponsor), that violates the TiC regulations
  - If a plan sponsor of a self-funded plan enters into a written agreement with the TPA of the self-funded plan under which the TPA will publically publish the machine-readable files and the TPA fails to do so, it is the plan (not the TPA) that violates the TiC regulations. The plan sponsor may be able to protect itself through indemnification

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Machine-Readable File

- Is the plan sponsor required to post the machine-readable files on the plan sponsor's website? This depends
  - The regulations require posting the machine-readable files on a public website of the plan (not the plan sponsor). Most plans don't maintain public websites
  - If the insurer or TPA publishes the machine readable files on its public website, it doesn't appear that the plan sponsor has to include the machine-readable files (or links) on its own public website
  - For self-funded plans that are administered by BCBSM, the plan sponsor will need to link to these files on its website because BCBSM will host these files in the "group portal" (which is not a public website)

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No Surprises Act

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Background of Emergency Services Under the ACA

- Non-grandfathered group health plans that provide any benefits with respect to emergency services must cover those services as follows:
  - Without prior authorization requirements (even if provided OON)
  - Without regard to whether the provider was in-network
  - May not impose any administrative requirement or coverage limitation that is more restrictive than those for in-network emergency services
  - Must comply with certain cost-sharing limitations
    - Copays and coinsurance can't be higher for OON than in-network services
    - Plan must satisfy a minimum payment amount for OON services

Overview of the No Surprises Act (NSA)

- The NSA provides protections with respect to surprise (balance) billing and participant cost-sharing in the following situations:
  - Emergency services provided at non-participating (out-of-network) facilities or by non-participating providers
  - Non-emergency services provided at participating (in-network) facilities by non-participating providers
  - Air ambulance services provided by non-participating providers
- The NSA also provides an independent dispute resolution (IDR) program to resolve payment disputes between providers and plans

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Coverage of Emergency Services Under the NSA

- If a group health plan (either grandfathered or non-grandfathered) covers benefits for any emergency services, those services must be covered:
  - Without any prior authorization requirement, even if provided OON
  - Without regard to whether the provider or facility is in-network
  - Without regard to any other term or condition of coverage, other than:
    - Exclusions or coordination of benefits (to the extent that it is not inconsistent with benefits for an emergency medical condition—i.e., "true ER lists")
    - Waiting period
    - Applicable cost-sharing

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Overview of the No Surprises Act (NSA)

- Effective dates:
  - For providers and facilities – January 1, 2022
  - For group health plans – the first day of the first plan year beginning on or after January 1, 2022

NQTL Comparative Analysis under the MHPAEA

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Financial Requirements and Quantitative Treatment Limitations

- A plan cannot apply a financial requirement or quantitative treatment limitation on MH/SUD benefits that is more restrictive than the *predominant level* of the financial requirement or quantitative treatment limitation that applies to *substantially all* of the M/S benefits in the same *classification*
  - Examples of financial requirements include deductibles, copayments, coinsurance and out-of-pocket maximums
  - Examples of quantitative treatment limitations include annual, episode, day and visit limits

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Non-Quantitative Treatment Limits (NQTLs)

- Under the terms of a plan (as written and operated), any processes, strategies, evidentiary standards, or other factors used to apply NQTLs to MH/SUD benefits in a *classification* must be comparable to (and applied no more stringently than) the processes, strategies, evidentiary standards, or other factors used in applying the NQTLs to M/S benefits in the same classification

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NQTL Examples

- Medically appropriate limitations
- Medically necessary limitations
- Neuropsychological testing limitations
- Variations in concurrent review
- Exclusion for Bipolar Disorder
- Managed care carve-out arrangements
- Exclusion for anti-depressant prescription drugs
- Penalties for failure to obtain pre-approval for treatment
- Requirement for pre-authorization for only MH/SUD benefits
- In-person utilization review for MH/SUD benefits
- Utilization-review requirements for inpatient treatment for MH/SUD benefits
- "Fail-first" requirement for inpatient treatment
- "Fail-first" requirement for medication assisted treatment
- Exclusion of court-ordered treatment for SUD benefits
- Exclusion of coverage for developmental disabilities
- Exclusion of nutritional counseling for anorexia nervosa
- Exclusion of out-of-network inpatient treatment disorders
- Exclusion of treatment at residential facilities
- Exclusion of treatment in non-hospital settings
- Wilderness therapy treatment exclusion

Testing Classifications

Classifications

- Inpatient, in-network
- Inpatient, out-of-network
- Outpatient, in-network
- Outpatient, out-of-network
- Emergency care
- Prescription drugs

Sub-classifications

- Network providers may be sub-classified by each network tier (if applicable)
- Outpatient benefits can be sub-classified into: (1) office visits; and (2) all other outpatient items and services

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Comparative Analysis

- The CAA amended ERISA, the Internal Revenue Code and the Public Health Service Act to require insurers and plans to perform an analysis of the NQTLs imposed by the plan:
  - It appears that all group health plans (those sponsored by private employers, church employers and non-federal governmental employers) are subject to the comparative analysis requirement (if the plan provides coverage of MH/SUD benefits)
  - For fully insured group health plans, the insurer must perform this analysis
  - For self-funded group health plans, the plan sponsor must perform this analysis

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Comparative Analysis

- For plans that provide MH/SUD benefits and impose NQTLs on those MH/SUD benefits, the insurer or the plan *must perform and document a comparative analysis of the design and application of the NQTLs*

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Comparative Analysis

- The comparative analysis must demonstrate that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to MH/SUD benefits (in writing *and in operation*) are comparable to, and are applied no more stringently than the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to M/S benefits in the same classification

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Disclosure to the Federal Government

- Beginning February 10, 2021 the insurer or plan must provide the DOL, IRS, or HHS with the comparative analysis upon request along with the following information:
  - Specific plan or coverage terms regarding the NQTLs and a description of all MH/SUD benefits to which each term applies
  - The factors used to determine that the NQTLs will apply to MH/SUD benefits and M/S benefits
  - The evidentiary standards (or any other source or evidence) relied upon to develop these factors
  - The specific findings and conclusions reached by the insurer or the plan, including any results of the analyses that indicate compliance or non-compliance

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Penalties

- If the DOL, IRS, or HHS determines the plan's NQTLs are not compliant with the MHPAEA:
  - The insurer or plan must specify to the DOL/IRS/HHS the actions the insurer or plan will take to become compliant; and
  - The insurer or plan must demonstrate compliance within 45 days of the initial determination of non-compliance by the DOL/IRS/HHS
- If the DOL/IRS/HHS makes another determination of non-compliance after this 45-day period, within 7 days of this second determination, the plan must notify all participants that it does not comply with the MHPAEA

Annual Report to Congress

- The DOL/IRS/HHS must file an annual report to Congress (which is made publically available) that includes the following information:
  - A summary of the comparative analyses requested, *including the specific identity of the insurer or the plan*, determined not to be in compliance
  - Conclusions as to whether each insurer or plan submitted sufficient information to review the comparative analysis and, if so, conclusions as to whether and why the insurer or plan was in compliance
  - Specifications for additional information requests
  - Action items taken by plans to achieve compliance in 45-day period

Nonopioid Directive Form

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Background

- In 2018, Michigan passed Public Act 554 of 2018, which required the Michigan Department of Health and Human Services (MDHHS) to publish a nonopioid directive form that allows patients (or a patient's representative) to opt-out of being administered or prescribed an opioid
  - There is an exception if the patient is in a hospital setting or outside the hospital in the case of an emergency in which an opioid may be administered if, in the prescriber's professional opinion, the opioid is medically necessary

Background

- On March 23, 2022, Michigan passed Public Act 42 of 2022, which requires insurers to provide this form upon enrollment for insureds beginning with policies that are delivered, executed, issued, amended, adjusted, or renewed after June 30, 2022 (including out-of-state policies covering residents of Michigan)

NONOPIOID DIRECTIVE
Michigan Department of Health and Human Services
Required by MCL 333.9145 effective 3/28/2019

MUST BE INCLUDED IN THE PATIENT'S MEDICAL RECORD

Patient Name	Date of Birth
Other names used by patient	Preferred language of patient
Emergency Contact	Name of primary care provider
Drug allergies	

The patient above must not be administered an opioid or offered a prescription for an opioid while this directive is in effect.

- An individual who has executed a nonopioid directive on their own behalf may revoke the directive at any time and in any way they are able to communicate their intent to revoke the form.
- A guardian or patient's advocate can revoke at any time by issuing a revocation in writing and providing notice of the revocation to the individual's health professional or their delegate.
- This directive does not apply to:
  - A patient receiving opioids for substance use disorder treatment;
  - A patient who is in hospice;
  - A patient is being treated at a hospital, or in a setting outside of a hospital in the case of an emergency, and, in the prescriber's professional opinion, the administration of the opioid is medically necessary to treat the individual.

Signature of patient, or if the patient is a minor, parent	Date
Printed name of Patient	Date
Signature of guardian or patient's advocate, if applicable	Date
Printed name of parent/guardian/patient's advocate, if applicable	Date

The Michigan Department of Health and Human Services (MDHHS) does not discriminate against any individual or group because of race, religion, age, national origin, color, height, weight, marital status, genetic information, sex, sexual orientation, gender identity or expression, political beliefs or disability.

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Impact on Group Health Plans

- No direct effect
- For fully insured group health plans, we expect that the insurer will rely on the employer-plan sponsor to provide the nonopioid directive form in its initial and open enrollment materials
- For self-funded group health plans, there is no requirement to provide the form (this state law would likely be preempted by ERISA), but employers may want to consider voluntarily providing the directive form in the plan's initial and open enrollment materials

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Coverage of Treatment for Autism Spectrum Disorders

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Background

- On April 28, 2022, the Department of HHS issued regulations regarding coverage of Essential Health Benefits (EHBs) by policies issued in the individual and small group markets with respect to "presumptively discriminatory practices"
- To overcome the presumption, insurers must demonstrate that clinical evidence justifies the differential treatment or it is required by federal law
- Fully insured group health plans in the large group market and self-funded group health plans are not subject to the EHB regulations

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Background

- Presumptively discriminatory practices based on age:
  - Limitations on hearing aid coverage
  - **Autism Spectrum Disorder (ASD) limitations based on age**
  - Age limits for infertility treatment coverage when treatment is clinically effective for the age group
- Presumptively discriminatory practices based on health conditions:
  - Foot care based on a diabetes diagnosis
  - Access to prescription drugs for chronic health conditions (adverse tiering)

ASD Coverage

"Age limits are presumptively discriminatory under §156.125 when applied to services that are covered as EHB and there is no clinical basis for the age limitation. A plan subject to §156.125 that covers diagnoses and treatment of ASD as an EHB, but limits such coverage in its plan benefit design based on age is presumptively discriminatory [in violation of] §156.125 unless the limitation is clinically based."

Impact on Group Health Plans

- Only direct effect on fully insured policies issued in the small group market in states that classify ASD benefits as EHBs (which it is in Michigan, as a "habilitative service")
- Indirect effect on fully insured policies issued in the large group market and self-funded plans:
  - For fully insured plans, coverage of ASD benefits will be controlled by the carrier
  - For self-funded plans, the employer-sponsor may have more control, but may still be subject to the TPA's administrative practices

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Blue Cross Blue Shield of Michigan

- From a BCBSM webinar on May 12, 2022: “Blue Cross will follow the recently updated state and federal requirements regarding the removal of age limits for autism spectrum disorder services for all underwritten [(fully insured)] and self-funded groups that provide autism coverage.”
- Effective January 1, 2022 (and included in 2023 plan certificates)

Questions?

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