

## **Title I – No Surprises Act**

### **Section 101. Short title.**

Section 101 states that this title may be cited as the “No Surprises Act”.

### **Section 102. Health insurance requirements regarding surprise medical billing.**

Section 102 requires health plans to hold patients harmless from surprise medical bills. Patients are only required to pay the in-network cost-sharing (i.e., co-payment, coinsurance and deductibles) amount for out-of-network emergency care, for certain ancillary services provided by out-of-network providers at in-network facilities, and for out-of-network care provided at in-network facilities without the patient’s informed consent. It also requires that patients’ in-network cost-sharing payments for out-of-network surprise bills are attributed to a patient’s in-network deductible.

### **Section 103. Determination of out-of-network rates to be paid by health plans; Independent dispute resolution process.**

Section 103 provides for a 30-day open negotiation period for providers and payers to settle out-of-network claims. It also states that if the parties are unable to reach a negotiated agreement, they may access a binding arbitration process – referred to as Independent Dispute Resolution (IDR) – in which one offer prevails. Providers may batch similar services in one proceeding when claims are from the same payer. The IDR process will be administered by independent, unbiased entities with no affiliation to providers or payers. The IDR entity is required to consider the market-based median in-network rate, alongside relevant information brought by either party, information requested by the reviewer, as well as factors such as the provider’s training and experience, patient acuity and the complexity of furnishing the item or service, in the case of a provider that is a facility, the teaching status, case mix and scope of services of such facility, demonstrations of good faith efforts (or lack of good faith efforts) to enter into a network agreement, prior contracted rates during the previous four plan years, and other items. Billed charges and public payer rates are excluded from consideration. Following IDR, the party that initiated the IDR may not take the same party to IDR for the same item or service for 90 days following a determination by the IDR entity, in order to encourage settlement of similar claims, but all claims that occur during that 90-day period may still be eligible for IDR upon completion of the 90-day period.

### **Section 104. Health care provider requirements regarding surprise medical billing.**

Section 104 prohibits out-of-network facilities and providers from sending patients surprise bills for more than the in-network cost-sharing amount, in the surprise billing circumstances defined in Sec. 102. It also prohibits certain out-of-network providers from surprise billing patients unless the provider gives the patient notice of their network status and an estimate of charges 72 hours prior to receiving out-of-network services and the patient provides consent to receive out-of-network care. In the case of appointments made within 72 hours of receiving services, the patient must receive the notice the day the appointment is made and consent to receive out-of-network care.

### **Section 105. Ending surprise air ambulance bills.**

Section 105 states that patients are held harmless from surprise air ambulance medical bills. Patients are only required to pay the in-network cost-sharing amount for out-of-network air ambulances, and that cost-sharing amount is applied to their in-network deductible. Air ambulances are barred from sending patients surprise bills for more than the in-network cost-sharing amount. It also provides for a 30-day open negotiation period for air ambulance providers and payers to settle out-of-network claims. If the parties are unable to reach a negotiated agreement, they may access the binding arbitration, which is the same as outlined in Section 103, with additional factors to account for the cost of providing air ambulance service in rural and frontier areas.

**Section 106. Reporting requirements regarding air ambulance services.**

Section 106 requires air ambulance providers to submit two years of cost data to the Secretaries of Health and Human Services (HHS) and Transportation and insurers to submit two years of claims data related to air ambulance services to the Secretary of HHS. The section requires the Secretaries to publish a comprehensive report on the cost and claims data submitted, and it also establishes an advisory committee on air ambulance quality and patient safety.

**Section 107. Transparency regarding in-network and out-of-network deductibles and out-of-pocket limitations.**

Section 107 states that a group or individual health plan shall include on their plan or insurance identification card issued to the enrollee the amount of the in-network and out-of-network deductibles and the in-network and out-of-network out-of-pocket maximum limitations.

**Section 108. Implementing protections against provider discrimination.**

Section 108 requires the Secretaries of HHS, Labor, and Treasury to promulgate a rule no later than January 1, 2022 implementing protections against provider discrimination.

**Section 109. Reports.**

Section 109 requires the Secretary of HHS, in consultation with the Federal Trade Commission and Attorney General, to conduct a study no later than January 1, 2023 and annually thereafter for the following four years on the effects of the provisions in the Act. It also requires the Government Accountability Office (GAO) to submit to Congress a report on the impact of surprise billing provisions and a report on adequacy of provider networks.

**Section 110. Consumer protections through application of health plan external review in cases of certain surprise medical bills.**

Section 110 allows for an external review to determine whether surprise billing protections are applicable when there is an adverse determination by a health plan beginning no later than January 1, 2022.

**Section 111. Consumer protections through health plan requirement for fair and honest advance cost estimate.**

Section 111 requires health plans to provide an Advance Explanation of Benefits for scheduled services at least three days in advance to give patients transparency into which providers are expected to provide treatment, the expected cost, and the network status of the providers.

**Section 112. Patient protections through transparency and patient-provider dispute resolution.**

Section 112 states that health care providers and facilities must verify, three days in advance of service and not later than one day after scheduling of service, what type of coverage the patient is enrolled in and provide notification of a good faith estimate to the payer or patient whether or not the patient has coverage. It also requires the Secretary of HHS to establish a patient-provider dispute resolution process for uninsured individuals no later than January 1, 2022.

**Section 113. Ensuring continuity of care.**

Section 113 states that if a provider changes network status, patients with complex care needs have up to a 90-day period of continued coverage at in-network cost-sharing to allow for a transition of care to an in-network provider.

**Section 114. Maintenance of price comparison tool.**

Section 114 requires health plans to offer a price comparison tool for consumers.

**Section 115. State All Payer Claims Databases.**

Section 115 establishes a grant program to create and improve State All Payer Claims Databases. It also requires recipients of the grants from this program to make data available to authorized users, including researchers, employers, health insurance issuers, third-party administrators, and health care providers for quality improvement and cost-containment purposes. The Secretary of HHS may waive these requirements if a State All Payer Claims Database is substantially in compliance. It also requires the Secretary of Labor to convene an advisory committee and develop a standardized format for voluntary reporting by group health plans to State All Payer Claims Databases.

**Section 116. Protecting patients and improving the accuracy of provider directory information.**

Section 116 requires health plans to have up-to-date directories of their in-network providers, which shall be available to patients online, or within one business day of an inquiry. If a patient provides documentation that they received incorrect information from a plan about a provider's network status prior to a visit, the patient will only be responsible for the in-network cost-sharing amount.

**Section 117. Advisory committee on ground ambulance and patient billing.**

Section 117 requires the Secretaries HHS, Labor, and Treasury to establish an advisory committee for reviewing options to improve disclosure of charges and fees for ground ambulance services, inform consumers of insurance options for such services, and protect consumers from surprise billing. It also requires a report on recommendations from the committee not later than 180 days after first meeting.

**Section 118. Implementation funding.**

Section 118 provides funding to the Secretaries of HHS, Labor, and Treasury for purposes of carrying out the amendments made by the No Surprises Act, including preparing, drafting, and issuing proposed and final regulations or interim regulations; preparing, drafting, and issuing guidance and public information; preparing and holding public meetings; preparing, drafting, and

publishing reports; enforcement of such provisions; reporting, collection and analysis of data; establishment and implementation of processes for independent dispute resolution and implementation of patient-provider dispute resolution; conducting audits, and other administrative duties necessary for implementation. Each of the Secretaries shall report annually to Congress on the funds expended under this section.

## **Title II – Transparency**

### **Section 201. Increasing transparency by removing gag clauses on price and quality information.**

Section 201 bans gag clauses in contracts between providers and health plans that prevent enrollees, plan sponsors, or referring providers from seeing cost and quality data on providers. It also bans gag clauses in contracts between providers and health insurance plans that prevent plan sponsors from accessing de-identified claims data that could be shared, under Health Insurance Portability and Accountability Act (HIPAA) business associate agreements, with third parties for plan administration and quality improvement purposes.

### **Section 202. Disclosure of direct and indirect compensation for brokers and consultants to employer-sponsored health plans and enrollees in plans on the individual market.**

Section 202 requires health benefit brokers and consultants to disclose to plan sponsors any direct or indirect compensation the brokers and consultants may receive for referral of services. The section requires health benefit brokers to disclose to enrollees in the individual market or enrollees purchasing short-term limited duration insurance any direct or indirect compensation the brokers may receive for referral of coverage. It also establishes a disclosure requirement for compensation that is not known at the time a contract is signed.

### **Section 203. Strengthening parity in mental health and substance use disorder benefits.**

Section 203 requires group health plans and health insurance issuers offering coverage in the individual or group markets to conduct comparative analyses of the nonquantitative treatment limitations used for medical and surgical benefits as compared to mental health and substance use disorder benefits. It requires the Secretaries of HHS, Labor, and the Treasury to request comparative analyses of at least 20 plans per year that involve potential violations of mental health parity, complaints regarding noncompliance with mental health parity, and any other instances in which the Secretaries determine appropriate. If, upon review of the analysis, the Secretaries of HHS, Labor, and the Treasury find that a plan or coverage offered by an issuer is out of compliance with mental health parity law, the Secretary must specify corrective actions for the plan or coverage to come into compliance, which the plan will have 45 days to implement. If the plan is still not in compliance after those 45 days, the plan shall notify all individuals enrolled in noncompliance plans within seven days. Finally, Section 203 requires the Secretaries of HHS, Labor, and the Treasury to publish an annual report with a summary of the comparative analyses.

### **Section 204. Reporting on pharmacy benefits and drug costs.**

Section 204 requires health plans to report information on plan medical costs and prescription drug spending to the Secretaries of HHS, Labor, and the Treasury. It also states that the Assistant Secretary of Planning and Evaluation, in coordination with the Office of the Inspector General,

shall publish a report on the HHS website on prescription drug pricing trends and the contribution to health insurance premiums 18 months after the date of enactment, and every two years thereafter.

### **Title III – Public Health Provisions**

#### **Subtitle A – Extenders Provisions**

##### **Section 301. Extension for community health centers, the National Health Service Corps, and teaching health centers that operate GME programs.**

Extends mandatory funding for community health centers, the National Health Service Corps, and the Teaching Health Center Graduate Medical Education Program at current levels for each of fiscal years 2021 through 2023.

##### **Section 302. Diabetes programs.**

Extends mandatory funding for the Special Diabetes Program for Type I Diabetes and the Special Diabetes Program for Indians at current levels for each of fiscal years 2021 through 2023.

#### **Subtitle B – Strengthening Public Health**

##### **Section 311. Improving awareness of disease prevention.**

Section 311 authorizes a national campaign to increase awareness and knowledge of the safety and effectiveness of vaccines for the prevention and control of diseases, to combat misinformation, and to disseminate scientific and evidence-based vaccine-related information. It also directs the Department of HHS to expand and enhance, and, as appropriate, establish and improve, programs and activities to collect, monitor, and analyze vaccination coverage data (the percentage of people who have had certain vaccines). The section also requires the National Vaccine Advisory Committee to update, as appropriate, the report entitled, “Assessing the State of Vaccine Confidence in the United States: Recommendations from the National Vaccine Advisory Committee.” Finally, it authorizes grants for the purpose of planning, implementation, and evaluation of activities to address vaccine-preventable diseases, and for research on improving awareness of scientific and evidence-based vaccine-related information.

##### **Section 312. Guide on evidence-based strategies for public health department obesity prevention programs.**

Section 312 authorizes HHS to develop and disseminate guides on evidence-based obesity prevention and control strategies for State, territorial, and local health departments and Indian tribes and tribal organizations.

##### **Section 313. Expanding capacity for health outcomes.**

Section 313 authorizes the provision of technical assistance and grants to evaluate, develop, and expand the use of technology-enabled collaborative learning and capacity building models to increase access to specialized health care services in medically underserved areas and for medically underserved populations.

**Section 314. Public health data system modernization.**

Section 314 requires HHS to expand, enhance, and improve public health data systems used by the Centers for Disease Control and Prevention (CDC). It also requires HHS to award grants to State, local, Tribal, or territorial public health departments for the modernization of public health data systems in order to assist public health departments in assessing current data infrastructure capabilities and gaps; to improve secure public health data collection, transmission, exchange, maintenance, and analysis; to enhance the interoperability of public health data systems; to support and train related personnel; to support earlier disease and health condition detection; and to develop and disseminate related information and improved electronic case reporting. Section 314 also requires the Secretary of HHS to develop and submit to Congress a coordinated strategy and accompanying implementation plan that identifies and demonstrates measures utilized to carry out such activities, and requires HHS to consult with State, local, Tribal, and territorial health departments and other appropriate public or private entities regarding the plan and grant program to modernize public health data systems pursuant to this section.

**Section 315. Native American suicide prevention.**

Section 315 ensures states consult with Indian tribes, tribal organizations, urban Indian organizations, and Native Hawaiian Health Care Systems in developing youth suicide early intervention and prevention strategies.

**Section 316. Reauthorization of the Young Women's Breast Health Education and Awareness Requires Learning Young Act of 2009.**

Section 316 reauthorizes the young women's breast health awareness and education program at \$9 million for each of fiscal years 2022 through 2026.

**Section 317. Reauthorization of school-based health centers.**

Section 317 reauthorizes the School-Based Health Center program for fiscal years 2022 through 2026.

**Subtitle C – FDA Amendments****Section 321. Rare pediatric disease priority review voucher extension.**

Section 321 allows the Food and Drug Administration (FDA) to continue to award priority review vouchers for drugs that treat rare pediatric diseases and are designated no later than September 30, 2024, and approved no later than September 30, 2026.

**Section 322. Conditions of use for biosimilar biological products.**

Section 322 clarifies that biosimilar applicants can include information in biosimilar submissions to show that the proposed conditions of use for the biosimilar product have been previously approved for the reference product.

**Section 323. Orphan drug clarification.**

Section 323 clarifies that the clinical superiority standard applies to all drugs with an orphan drug designation for which an application is approved after the enactment of the FDA Reauthorization Act of 2017, regardless of the date of the orphan drug designation.

**Section 324. Modernizing the labeling of certain generic drugs.**

Section 324 allows FDA to identify and select certain covered generic drugs for which labeling updates would provide a public health benefit and require sponsors of such drug applications to update labeling. It also requires FDA to report on the number of covered drugs and a description of the types of drugs selected for labeling changes, and the rationale for such recommended changes, and to provide recommendations for modifying the program under this section.

**Section 325. Biological product patent transparency.**

Section 325 increases transparency of patent information for biological products by requiring patent information to be submitted to FDA and published in the “Purple Book.” It also codifies the publication of the “Purple Book” as a single, searchable list of information about each licensed biological product, including marketing and licensure status, patent information, and relevant exclusivity periods.

**Subtitle D – Technical Corrections****Section 331. Technical corrections.**

Section 331 makes technical amendments to the Coronavirus Aid, Relief, and Economic Security Act.