(2) APPLICABILITY OF OTHER LAWS.—For purposes of subpart 2 of part B of title IV of the Social Security Act (42 U.S.C. 629 et seq.), each report required by paragraph (1) of this subsection shall be considered to be required by section 432(a)(8) of such Act (42 U.S.C. 629b(a)(8)), and shall contain such additional information as the Secretary may require.

(e) DEFINITION OF STATE.—In this section, the term "State" has the meaning given the term in section 431(a)(4) of the Social Security Act (42 U.S.C. 629a(a)(4)).

(f) RENAMING OF TITLE IV–B–2 OF THE SOCIAL SECURITY ACT.—The subpart heading for subpart 2 of part B of title IV of the Social Security Act is amended by striking "**Promoting Safe and Stable Families**" and inserting "**MaryLee Allen Promoting Safe and Stable Families Program**".

(g) EFFECTIVE DATE.—This section and the amendments made by this section shall take effect as if included in the Bipartisan Budget Act of 2018 on the date of the enactment of such Act.

(h) TECHNICAL CORRECTION.—Section 50701 of the Bipartisan Budget Act of 2018 (42 U.S.C. 1305 note; Public Law 115–123) is amended by striking "Bipartisan Budget Act of 2018" and inserting "Family First Prevention Services Act".

SEC. 603. MINIMUM AGE OF SALE OF TOBACCO PRODUCTS.

(a) IN GENERAL.—Section 906(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)) is amended—

(1) in paragraph (3)(A)(ii), by striking "18 years" and inserting "21 years"; and

(2) by adding at the end the following:

"(5) MINIMUM AGE OF SALE.—It shall be unlawful for any retailer to sell a tobacco product to any person younger than 21 years of age.".

(b) REGULATIONS.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall publish in the Federal Register a final rule to update the regulations issued under chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387 et seq.) as appropriate, only to carry out the amendments made by subsection (a), including to update all references to persons younger than 18 years of age in subpart B of part 1140 of title 21, Code of Federal Regulations, and to update the relevant age verification requirements under such part 1140 to require age verification for individuals under the age of 30. Such final rule shall—

(A) take full effect not later than 90 days after the date on which such final rule is published; and

(B) be deemed to be in compliance with all applicable provisions of chapter 5 of title 5, United States Code and all other provisions of law relating to rulemaking procedures.

(2) OTHER REGULATIONS.—Prior to making amendments to part 1140 of title 21, Code of Federal Regulations other than the amendments described in paragraph (1), the Secretary shall promulgate a proposed rule in accordance with chapter 5 of title 5, United States Code.

(c) NOTIFICATION.—Not later than 90 days after the date of enactment of this Act, the Secretary shall provide written notification to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding the progress of the Department of Health and Human Services towards promulgating the final rule under subsection (b). If, 180 days after the date of enactment of this Act, such rule has not been promulgated in accordance with subsection (b), the Secretary shall provide a written notification and a justification for the delay in rulemaking to such committees.

(d) PENALTIES FOR VIOLATIONS.—

(1) IN GENERAL.—Section 103(q)(2) of the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31) is amended—

(A) in subparagraph (A), in the matter preceding clause (i), by inserting "section 906(d)(5) or of" after "violations of"; and

(B) in subparagraph (C), by inserting "section 906(d)(5) or of" after "a retailer of".

(2) REPEATED VIOLATIONS.—Section 303(f)(8) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(8)) is amended by inserting "section 906(d)(5) or of" after "repeated violations of".

(3) MISBRANDED PRODUCTS.—Section 903(a)(7)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387c) is amended by inserting "section 906(d)(5) or of" after "violation of".

SEC. 604. SALE OF TOBACCO PRODUCTS TO INDIVIDUALS UNDER THE AGE OF 21.

(a) IN GENERAL.—Section 1926 of the Public Health Service Act (42 U.S.C. 300x–26) is amended—

(1) in the heading—

(A) by striking "**STATE LAW REGARDING**"; and

(B) by striking "**18**" and inserting "**21**";

(2) by striking subsections (a) and (d);

(3) by redesignating subsections (b) and (c) as subsections (a) and (b), respectively;

(4) by amending subsection (a), as so redesignated, to read as follows:

"(a) IN GENERAL.—A funding agreement for a grant under section 1921 is that the State involved will—

"(1) annually conduct random, unannounced inspections to ensure that retailers do not sell tobacco products to individuals under the age of 21; and

"(2) annually submit to the Secretary a report describing—

"(A) the activities carried out by the State to ensure that retailers do not sell tobacco products to individuals under the age of 21;

"(B) the extent of success the State has achieved in ensuring that retailers do not sell tobacco products to individuals under the age of 21; and

"(C) the strategies to be utilized by the State to ensure that retailers do not sell tobacco products to individuals under the age of 21 during the fiscal year for which the grant is sought.";

(5) in subsection (b), as so redesignated—

(A) by striking paragraphs (1), (2), (3), and (4);

(B) by striking "Before making" and inserting the following:

"(1) IN GENERAL.—Before making";

(C) by striking "for the first applicable fiscal year or any subsequent fiscal year";

(D) by striking "subsections (a) and (b)" and inserting "subsection (a)";

(E) by striking "equal to—" and inserting "up to 10 percent of the amount determined under section 1933 for the State for the applicable fiscal year."; and

(F) by adding at the end the following:

"(2) LIMITATION.—

"(A) IN GENERAL.—A State shall not have funds withheld pursuant to paragraph (1) if such State for which the Secretary has made a determination of noncompliance under such paragraph—

"(i) certifies to the Secretary by May 1 of the fiscal year for which the funds are appropriated, consistent with subparagraph (B), that the State will commit additional State funds, in accordance with paragraph (1), to ensure that retailers do not sell tobacco products to individuals under 21 years of age;

"(ii) agrees to comply with a negotiated agreement for a corrective action plan that is approved by the Secretary and carried out in accordance with guidelines issued by the Secretary; or

"(iii) is a territory that receives less than $1,000,000 for a fiscal year under section 1921.

"(B) CERTIFICATION.—

"(i) IN GENERAL.—The amount of funds to be committed by a State pursuant to subparagraph (A)(i) shall be equal to 1 percent of such State's substance abuse allocation determined under section 1933 for each percentage point by which the State misses the retailer compliance rate goal established by the Secretary.

"(ii) STATE EXPENDITURES.—For a fiscal year in which a State commits funds as described in clause (i), such State shall maintain State expenditures for tobacco prevention programs and for compliance activities at a level that is not less than the level of such expenditures maintained by the State for the preceding fiscal year, plus the additional funds for tobacco compliance activities required under clause (i). The State shall submit a report to the Secretary on all State obligations of funds for such fiscal year and all State expenditures for the preceding fiscal year for tobacco prevention and compliance activities by program activity by July 31 of such fiscal year.

"(iii) DISCRETION.—The Secretary shall exercise discretion in enforcing the timing of the State obligation of the additional funds required by the certification described in subparagraph (A)(i) as late as July 31 of such fiscal year.

"(C) FAILURE TO CERTIFY.—If a State described in subparagraph (A) fails to certify to the Secretary pursuant

to subparagraph (A)(i) or enter into, or comply with, a negotiated agreement under subparagraph (A)(ii), the Secretary may take action pursuant to paragraph (1)."; and

(6) by adding at the end the following:

"(c) IMPLEMENTATION OF REPORTING REQUIREMENTS.—

"(1) TRANSITION PERIOD.—The Secretary shall—

"(A) not withhold amounts under subsection (b) for the 3-year period immediately following the date of enactment of division N of the Further Consolidated Appropriations Act, 2020; and

"(B) use discretion in exercising its authority under subsection (b) during the 2-year period immediately following the 3-year period described in subparagraph (A), to allow for a transition period for implementation of the reporting requirements under subsection (a)(2).

"(2) REGULATIONS OR GUIDANCE.—Not later than 180 days after the date of enactment of division N of the Further Consolidated Appropriations Act, 2020, the Secretary shall update regulations under part 96 of title 45, Code of Federal Regulations or guidance on the retailer compliance rate goal under subsection (b), the use of funds provided under section 1921 for purposes of meeting the requirements of this section, and reporting requirements under subsection (a)(2).

"(3) COORDINATION.—The Secretary shall ensure the Assistant Secretary for Mental Health and Substance Use coordinates, as appropriate, with the Commissioner of Food and Drugs to ensure that the technical assistance provided to States under subsection (e) is consistent with applicable regulations for retailers issued under part 1140 of title 21, Code of Federal Regulations.

"(d) TRANSITIONAL GRANTS.—

"(1) IN GENERAL.—The Secretary shall award grants under this subsection to each State that receives funding under section 1921 to ensure compliance of each such State with this section.

"(2) USE OF FUNDS.—A State receiving a grant under this subsection—

"(A) shall use amounts received under such grant for activities to plan for or ensure compliance in the State with subsection (a); and

"(B) in the case of a State for which the Secretary has made a determination under subsection (b) that the State is prepared to meet, or has met, the requirements of subsection (a), may use such funds for tobacco cessation activities, strategies to prevent the use of tobacco products by individuals under the age of 21, or allowable uses under section 1921.

"(3) SUPPLEMENT NOT SUPPLANT.—Grants under this subsection shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under paragraph (2).

"(4) AUTHORIZATION OF APPROPRIATIONS.—To carry out this subsection, there are authorized to be appropriated $18,580,790 for each of fiscal years 2020 through 2024.

"(5) SUNSET.—This subsection shall have no force or effect after September 30, 2024.

"(e) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to States related to the activities required under this section.".

(b) REPORT TO CONGRESS.—Not later than 3 years after the date of enactment of this Act, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the status of implementing the requirements of section 1926 of the Public Health Service Act (42 U.S.C. 300x–26), as amended by subsection (a), and a description of any technical assistance provided under subsection (e) of such section, including the number of meetings requested and held related to technical assistance.

(c) CONFORMING AMENDMENT.—Section 212 of division D of the Consolidated Appropriations Act, 2010 (Public Law 111–117) is repealed.

SEC. 605. BIOLOGICAL PRODUCT DEFINITION.

Section 351(i)(1) of the Public Health Service Act (42 U.S.C. 262(i)(1)) is amended by striking "(except any chemically synthesized polypeptide)".

SEC. 606. PROTECTING ACCESS TO BIOLOGICAL PRODUCTS.

Section 351(k)(7) of the Public Health Service Act (42 U.S.C. 262(k)(7)) is amended by adding at the end the following:

"(D) DEEMED LICENSES.—

"(i) NO ADDITIONAL EXCLUSIVITY THROUGH DEEMING.—An approved application that is deemed to be a license for a biological product under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 shall not be treated as having been first licensed under subsection (a) for purposes of subparagraphs (A) and (B).

"(ii) APPLICATION OF LIMITATIONS ON EXCLUSIVITY.—Subparagraph (C) shall apply with respect to a reference product referred to in such subparagraph that was the subject of an approved application that was deemed to be a license pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

"(iii) APPLICABILITY.—The exclusivity periods described in section 527, section 505A(b)(1)(A)(ii), and section 505A(c)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act shall continue to apply to a biological product after an approved application for the biological product is deemed to be a license for the biological product under subsection (a) pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.".

SEC. 607. STREAMLINING THE TRANSITION OF BIOLOGICAL PRODUCTS.

Section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148) is amended—

(1) by striking "An approved application" and inserting the following:

"(A) IN GENERAL.—An approved application"; and

(2) by adding at the end the following: