I

115TH CONGRESS
2D SESSION

H. R. 5531

To provide for a comprehensive, multifaceted approach to preventing and treating opioid addiction.

IN THE HOUSE OF REPRESENTATIVES

APRIL 17, 2018

Mr. BUCHANAN (for himself and Mrs. MURPHY of Florida) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, the Budget, Veterans' Affairs, Oversight and Government Reform, and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To provide for a comprehensive, multifaceted approach to preventing and treating opioid addiction.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Opioid Emergency Response Act".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

SEC. 2. ALTERNATIVES TO OPIOIDS PRESCRIBING.

(a) ESTABLISHMENT.—Beginning not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services (in this Act referred to as the ''Secretary'') shall carry out a 5-year demonstration project under which payment shall be made under the hospital outpatient prospective payment system under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.) to participating hospitals for items and services furnished as alternatives to opioid medications to individuals enrolled under such part to treat conditions designated under subsection (c)(1) for purposes of evaluating the benefits of using, instead of opioid medications, such alternatives to treat in emergency departments such symptoms and conditions.

(b) EMERGENCY DEPARTMENTS.—

(1) SELECTION.—The Secretary shall select from hospitals with emergency departments voluntarily submitting applications under paragraph (4), not fewer than 30 hospitals with emergency departments, and not more than 50 hospitals with emer-

gency departments, for participation in the demonstration project.

(2) DIVERSITY.—In selecting hospitals with emergency departments, the Secretary shall ensure such hospitals and emergency departments are diverse in geography and size.

(3) VOLUNTARY PARTICIPATION.—Participation in the demonstration project under this section shall be on a voluntary basis.

(4) APPLICATIONS.—

(A) IN GENERAL.—To participate in the demonstration project, a hospital with an emergency department shall submit to the Secretary an application at such time, in such manner, and containing such information (in addition to the written commitment described in subparagraph (B)) as specified by the Secretary. The Secretary shall take such measures as is necessary to make available such application form to potential participants no later than 180 days after the date of the enactment of this Act.

(B) INFORMATION REQUIRED.—Each application submitted by a hospital under subparagraph (A) shall include a binding written commitment to participate in the demonstration

project for the duration of the project signed by the Chief Executive Officer of the hospital, the physician medical director of the emergency department of the hospital, the nursing director of the emergency department of the hospital, and the pharmacy director of the emergency department of the hospital.

(c) ELEMENTS OF DEMONSTRATION PROJECT.—Under the demonstration project, the following shall apply:

(1) The Secretary shall designate no fewer than five conditions or sets of symptoms that will be monitored during the demonstration project.

(2) The performance during each year of the demonstration project, with respect to such conditions designated under paragraph (1), of all emergency departments of hospitals participating in the demonstration project will be measured against the performance of such emergency departments during a base year, which shall represent the most recent set of full year data available before the first date of the demonstration project.

(3) The Secretary shall provide hospitals participating in the demonstration project with a description of clearly defined treatments that are con-

sidered alternatives to opioids to be applied for purposes of subsection (a).

(d) INCENTIVE PAYMENT.—Under the demonstration project, the Secretary shall create a payment structure under which hospitals participating in the demonstration project that increase the use of alternatives to opioids and decrease the use of opioids may receive a shared savings bonus in addition to what would otherwise be made for items and services furnished under subsection (a). The amount of such shared savings shall be based on the difference between readmission rates for individuals treated with an alternative to opioids at the emergency department of the participating hospital and the average rate of readmissions for individuals treated with opioids and discharged from a representative group of emergency departments of hospitals not participating in the demonstration project in the same region as the participating hospital over a period of five years.

(e) CLARIFICATION.—Nothing under this section shall prevent a health care provider from prescribing an opioid if an opioid is a medically necessary treatment.

(f) REPORTS TO CONGRESS.—

(1) INITIAL REPORT.—Not later than 180 days after the date of the enactment of this Act, the Sec-

retary shall submit to Congress a report that includes—

(A) the application form described in subsection (b)(4)(A) that is to be made available to potential participants; and

(B) a progress report with respect to designating the conditions under subsection (c)(1) and establishing the description of clearly defined treatments described in subsection (c)(3).

(2) PERIODIC DEMONSTRATION REPORTS.—Beginning after the first year of the demonstration project and annually thereafter for each year of the demonstration project and not later than one year after the completion of the demonstration, the Secretary shall submit to Congress a report that includes the following data for each hospital participating under the demonstration project:

(A) With respect to each condition or set of symptom designated under subsection (c)(1), the number of individuals treated.

(B) With respect to each such condition, the number of individuals treated only with an alternative to opioids.

(C) With respect to each such condition, the number of individuals treated first with an

alternative to opioids, followed by an opioid in the same visit.

(D) With respect to each such condition, the number of individuals treated only with an opioid.

(E) With respect to each individual described in subparagraph (A) treated for such a condition or set of symptoms, whether or not the individual involved returned to the emergency department of the hospital or an emergency department of a different hospital for the same condition or symptoms.

(F) The difference in cost between treating an individual with an alternative to opioid versus an opioid.

(G) Any additional information the Secretary determines necessary.

SEC. 3. OPIOIDS AND STOP PAIN INITIATIVE.

(a) ESTABLISHMENT.—There is established an Opioids and STOP Pain Initiative, to be administered by the Director of the National Institutes of Health, in coordination with other agencies, as appropriate, which shall include efforts to support research on the following:

(1) Section 108 of the Comprehensive Addiction and Recovery Act of 2016 (42 U.S.C. 284q–1),

known as the STOP Pain Act, which directs the National Institutes of Health to intensify and coordinate fundamental, translational, and clinical research with respect to—

(A) the understanding of pain;

(B) the discovery and development of therapies for chronic pain; and

(C) the development of alternatives to opioids for effective pain treatments.

(2) Developing improved options and evidence for medication-assisted treatment.

(3) Developing improved options and evidence for opioid overdose reversal treatments.

(4) The Federal Pain Research Strategy, including research that focuses on—

(A) novel drugs, non-addictive, and non-pharmacological treatments for pain;

(B) screening tools and outcome measure for assessments across the continuum of pain;

(C) national registries, datasets, and research networks;

(D) effective models of care delivery for pain management; and

(E) precision medicine methodology to prevent and treat pain.

(5) The components of the Department of Health and Human Services five-point strategy to address the opioid crisis that states: ''Providing support for cutting edge research on pain and addiction''.

(6) The pain therapy screening program established under subsection (c).

(7) Other elements that the Secretary of Health and Human Services may designate, in consultation with the Director of the National Institutes of Health.

(b) FUNDING FOR THE OPIOIDS AND STOP PAIN INITIATIVE.—

(1) IN GENERAL.—There is authorized to be appropriated, and there is appropriated, $500,000,000, to be used during the 5-fiscal-year period beginning in the fiscal year in which such funds are appropriated, to the National Institutes of Health Innovation Account to be used to administer the Opioids and STOP Pain Initiative established under subsection (a).

(2) EMERGENCY SPENDING.—

(A) IN GENERAL.—Amounts appropriated under paragraph (1) are designated as an emergency requirement pursuant to section 4(g) of

the Statutory Pay-As-You-Go Act of 2010 (2 U.S.C. 933(g)).

(B) DESIGNATION IN THE SENATE.—In the Senate, amounts appropriated under subsection (a) are designated as an emergency requirement pursuant to section 403(a) of S. Con. Res. 13 (111th Congress), the concurrent resolution on the budget for fiscal year 2010.

(c) PAIN THERAPY SCREENING PROGRAM.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall carry out through the National Institutes of Health a program to be known as the ''Pain Therapy Screening Program'' that focuses on the development of pain therapeutics.

(2) GRANTS.—The Secretary shall award grants under the program under paragraph (1) to eligible public and private nonprofit entities to support the development of new pre-clinical models for pain disorders, and the application of these models in drug, device, or other therapy screening.

(3) MODEL.—The program under this section shall be modeled after the Epilepsy Therapy Screening Program carried out by the National Institute of Neurological Disorders and Stroke.

(4) FEES.—The Secretary of Health and Human Services may assess reasonable fees on private pharmaceutical or medical device industry entities that utilize the program under this section to screen proprietary molecular compounds and devices. Such fees shall be paid to the Foundation for the National Institutes of Health and transferred to the NIH Innovation Account to be used for the Opioids and STOP Pain Initiative established under subsection (a).

(5) FUNDING.—The Director of the National Institutes of Health shall determine the amount, and allocate, funds from the amount appropriated under subsection (b), to carry out this section.

(d) FUNDING PROVISIONS.—

(1) SUPPLEMENT NOT SUPPLANT.—Amounts appropriated in this section (including the amendments made by this section) shall be used to supplement, not supplant, current funding for pain and opioid research at the National Institutes of Health.

(2) ACCEPTANCE OF DONATIONS.—Notwithstanding section 1342 of title 31, United States Code, the Secretary of Health and Human Services may accept donations (including from the pharmaceutical and medical device industries) to be used to

assist in carrying out programs and activities under this section (and the amendments made by this section). Such donations shall be paid to the Foundation for the National Institutes of Health and transferred to the NIH Innovation Account to be used for the Opioids and STOP Pain Initiative established under subsection (a).

(3) INCLUSION OF CONTRIBUTION AMOUNTS IN BASIC RESEARCH FOR PURPOSES OF RESEARCH CREDIT.—

(A) IN GENERAL.—Paragraph (6) of section 41(e) of the Internal Revenue Code of 1986 is amended by adding at the end the following new subparagraph:

''(E) OPIOIDS AND STOP PAIN INITIATIVE.—The National Institutes of Health, if the payment is made in support of the Opioids and STOP Pain Initiative, as established by the Opioids and STOP Pain Initiative Act.''.

(B) EFFECTIVE DATE.—The amendments made by this subsection shall apply to taxable years beginning after the date of the enactment of this Act.

(e) AUTHORITY.—Notwithstanding any other provision of the law, the Director of the National Institutes

of Health may use funds available under subsection (b) to enter into transactions (other than contracts, cooperative agreements, or grants) to carry out research identified pursuant to the Opioids and STOP Pain Initiative established under subsection (a).

(f) REPORTS.—

(1) ANNUAL REPORTS.—Not later than October 1 of each of fiscal years 2019 through 2026, the Director of the National Institutes of Health shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a report that includes—

(A) the amount obligated or expended in the fiscal year prior to the fiscal year in which the report is being submitted for each program or activity described in this section (or an amendment made by this section);

(B) a description of all such programs or activities carried out using funds provided under this section (or amendments); and

(C) a description of how such programs or activities are advancing public health, including

the impact on treating pain and addressing opioid misuse in the United States.

(2) ADDITIONAL REPORTS.—At the request of the Committee on Health, Education, Labor, and Pensions or the Committee on Appropriations of the Senate, or the Committee on Energy and Commerce or the Committee on Appropriations of the House of Representatives, the Director of the National Institutes of Health shall provide to the relevant committee an update in the form of testimony and additional reports concerning the allocation of funding under this section (or the amendments made by this section) or the description of the programs and activities carried out with such funding.

SEC. 4. VETERAN OVER-MEDICATION PREVENTION.

(a) REVIEW REQUIRED.—

(1) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, the Secretary of Veterans Affairs shall seek to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine under which the National Academies shall conduct a review of the deaths of all covered veterans who died by suicide during the five-year period ending on the date of the enactment of this Act, regardless of whether information relating

to such deaths has been reported by the Centers for Disease Control and Prevention.

(2) ELEMENTS.—The review required by paragraph (1) shall include the following:

(A) The total number of covered veterans who died by suicide during the five-year period ending on the date of the enactment of this Act.

(B) The total number of covered veterans who died by a violent death during such five-year period.

(C) The total number of covered veterans who died by an accidental death during such five-year period.

(D) A description of each covered veteran described in subparagraphs (A) through (C), including age, gender, race, and ethnicity.

(E) A comprehensive list of prescribed medications and legal or illegal substances as annotated on toxicology reports of covered veterans described in subparagraphs (A) through (C), specifically listing any medications that carried a black box warning, were prescribed for off-label use, were psychotropic, or carried warnings that included suicidal ideation.

(F) A summary of medical diagnoses by physicians of the Department of Veterans Affairs or physicians providing services to covered veterans through programs of the Department that led to the prescribing of medications referred to in subparagraph (E) in cases of post-traumatic stress disorder, traumatic brain injury, military sexual trauma, and other anxiety and depressive disorders.

(G) The number of instances in which a covered veteran described in subparagraph (A), (B), or (C) was concurrently on multiple medications prescribed by physicians of the Department or physicians providing services to veterans through programs of the Department to treat post-traumatic stress disorder, traumatic brain injury, military sexual trauma, other anxiety and depressive disorders, or instances of comorbidity.

(H) The number of covered veterans described in subparagraphs (A) through (C) who were not taking any medication prescribed by a physician of the Department or a physician providing services to veterans through a program of the Department.

(I) With respect to the treatment of post-traumatic stress disorder, traumatic brain injury, military sexual trauma, or other anxiety and depressive disorders, the percentage of covered veterans described in subparagraphs (A) through (C) who received a non-medication first-line treatment compared to the percentage of such veterans who received medication only.

(J) With respect to the treatment of covered veterans described in subparagraphs (A) through (C) for post-traumatic stress disorder, traumatic brain injury, military sexual trauma, or other anxiety and depressive disorders, the number of instances in which a non-medication first-line treatment (such as cognitive behavioral therapy) was attempted and determined to be ineffective for such a veteran, which subsequently led to the prescribing of a medication referred to in subparagraph (E).

(K) A description and example of how the Department determines and continually updates the clinical practice guidelines governing the prescribing of medications.

(L) An analysis of the use by the Department, including protocols or practices at med-

ical facilities of the Department, of systematically measuring pain scores during clinical encounters under the Pain as the 5th Vital Sign Toolkit of the Department and an evaluation of the relationship between the use of such measurements and the number of veterans concurrently on multiple medications prescribed by physicians of the Department.

(M) A description of the efforts of the Department to maintain appropriate staffing levels for mental health professionals, such as mental health counselors, marriage and family therapists, and other appropriate counselors, including—

(i) a description of any impediments to carry out the education, training, and hiring of mental health counselors and marriage and family therapists under section 7302(a) of title 38, United States Code, and strategies for addressing those impediments;

(ii) a description of the objectives, goals, and timing of the Department with respect to increasing the representation of such counselors and therapists in the be-

havioral health workforce of the Department, including—

(I) a review of eligibility criteria for such counselors and therapists and a comparison of such criteria to that of other behavioral health professions in the Department; and

(II) an assessment of the participation of such counselors and therapists in the mental health professionals trainee program of the Department and any impediments to such participation;

(iii) an assessment of the development by the Department of hiring guidelines for mental health counselors, marriage and family therapists, and other appropriate counselors;

(iv) a description of how the Department—

(I) identifies gaps in the supply of mental health professionals; and

(II) determines successful staffing ratios for mental health professionals of the Department;

(v) a description of actions taken by the Secretary, in consultation with the Director of the Office of Personnel Management, to create an occupational series for mental health counselors and marriage and family therapists of the Department and a timeline for the creation of such an occupational series; and

(vi) a description of actions taken by the Secretary to ensure that the national, regional, and local professional standards boards for mental health counselors and marriage and family therapists are comprised of only mental health counselors and marriage and family therapists and that the liaison from the Department to such boards is a mental health counselor or marriage and family therapist.

(N) The percentage of covered veterans described in subparagraphs (A) through (C) with combat experience or trauma related to combat experience (including military sexual trauma, traumatic brain injury, and post-traumatic stress).

(O) An identification of the medical facilities of the Department with markedly high prescription rates and suicide rates for veterans receiving treatment at those facilities.

(P) An analysis, by State, of programs of the Department that collaborate with State Medicaid agencies and the Centers for Medicare and Medicaid Services, including the following:

(i) An analysis of the sharing of prescription and behavioral health data for veterans.

(ii) An analysis of whether Department staff check with State prescription drug monitoring programs before prescribing medications to veterans.

(iii) A description of the procedures of the Department for coordinating with prescribers outside of the Department to ensure that veterans are not overprescribed.

(iv) A description of actions that the Department takes when a veteran is determined to be overprescribed.

(Q) An analysis of the collaboration of medical centers of the Department with medical

examiners' offices or local jurisdictions to determine veteran mortality and cause of death.

(R) An identification and determination of a best practice model to collect and share veteran death certificate data between the Department of Veterans Affairs, the Department of Defense, States, and tribal entities.

(S) A description of how data relating to death certificates of veterans is collected, determined, and reported by the Department of Veterans Affairs.

(T) An assessment of any patterns apparent to the National Academies of Sciences, Engineering, and Medicine based on the review conducted under paragraph (1).

(U) Such recommendations for further action that would improve the safety and well-being of veterans as the National Academies of Sciences, Engineering, and Medicine determine appropriate.

(3) COMPILATION OF DATA.—

(A) FORM OF COMPILATION.—The Secretary of Veterans Affairs shall ensure that data compiled under paragraph (2) is compiled in a manner that allows it to be analyzed across

all data fields for purposes of informing and updating clinical practice guidelines of the Department of Veterans Affairs.

(B) COMPILATION OF DATA REGARDING COVERED VETERANS.—In compiling data under paragraph (2) regarding covered veterans described in subparagraphs (A) through (C) of such paragraph, data regarding veterans described in each such subparagraph shall be compiled separately and disaggregated by year.

(4) COMPLETION OF REVIEW AND REPORT.—The agreement entered into under paragraph (1) shall require that the National Academies of Sciences, Engineering, and Medicine complete the review under such paragraph and submit to the Secretary of Veterans Affairs a report containing the results of the review not later than 180 days after entering into the agreement.

(b) REPORT.—Not later than 30 days after the completion by the National Academies of Sciences, Engineering, and Medicine of the review required under subsection (a), the Secretary of Veterans Affairs shall—

(1) submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans'

Affairs of the House of Representatives a report on the results of the review; and

(2) make such report publicly available.

(c) DEFINITIONS.—In this section:

(1) The term ''black box warning'' means a warning displayed on the label of a prescription drug that is designed to call attention to the serious or life-threatening risk of the prescription drug.

(2) The term ''covered veteran'' means a veteran who received hospital care or medical services furnished by the Department of Veterans Affairs during the five-year period preceding the death of the veteran.

(3) The term ''first-line treatment'' means a potential intervention that has been evaluated and assigned a high score within clinical practice guidelines.

(4) The term ''State'' means each of the States, territories, and possessions of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

SEC. 5. AMENDMENT RELATING TO THE ACCOUNT FOR THE STATE RESPONSE TO THE OPIOID ABUSE CRISIS.

Section 1003 of the 21st Century Cures Act (Public Law 114–255; 42 U.S.C. 290ee–3 note) is amended in subsection (b)(3), by adding at the end the following new subparagraph:

''(C) APPROPRIATIONS AFTER FISCAL YEAR 2018.—There is authorized to be appropriated, and there is appropriated, out of any monies in the Treasury not otherwise appropriated, to the Account For the State Response to the Opioid Abuse Crisis $500,000,000 for each of fiscal years 2019 through 2023.''.

SEC. 6. MENTAL HEALTH ACCESS IMPROVEMENT.

(a) COVERAGE OF SERVICES.—

(1) IN GENERAL.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) is amended—

(A) in subparagraph (FF), by striking ''and'' after the semicolon at the end;

(B) in subparagraph (GG), by inserting ''and'' after the semicolon at the end; and

(C) by adding at the end the following new subparagraph:

''(HH) marriage and family therapist services (as defined in subsection (jjj)(1)) and mental health counselor services (as defined in subsection (jjj)(3));''.

(2) DEFINITIONS.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

''Marriage and Family Therapist Services; Marriage and Family Therapist; Mental Health Counselor Services; Mental Health Counselor

''(jjj)(1) The term 'marriage and family therapist services' means services performed by a marriage and family therapist (as defined in paragraph (2)) for the diagnosis and treatment of mental illnesses, which the marriage and family therapist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed, as would otherwise be covered if furnished by a physician or as an incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services.

''(2) The term 'marriage and family therapist' means an individual who—

''(A) possesses a master's or doctoral degree which qualifies for licensure or certification as a marriage and family therapist pursuant to State law;

''(B) after obtaining such degree has performed at least 2 years of clinical supervised experience in marriage and family therapy; and

''(C) in the case of an individual performing services in a State that provides for licensure or certification of marriage and family therapists, is licensed or certified as a marriage and family therapist in such State.

''(3) The term 'mental health counselor services' means services performed by a mental health counselor (as defined in paragraph (4)) for the diagnosis and treatment of mental illnesses which the mental health counselor is legally authorized to perform under State law (or the State regulatory mechanism provided by the State law) of the State in which such services are performed, as would otherwise be covered if furnished by a physician or as incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services.

''(4) The term 'mental health counselor' means an individual who—

''(A) possesses a master's or doctor's degree in mental health counseling or a related field;

''(B) after obtaining such a degree has performed at least 2 years of supervised mental health counselor practice; and

''(C) in the case of an individual performing services in a State that provides for licensure or certification of mental health counselors or professional counselors, is licensed or certified as a mental health counselor or professional counselor in such State.''.

(3) PROVISION FOR PAYMENT UNDER PART B.—Section 1832(a)(2)(B) of the Social Security Act (42 U.S.C. 1395k(a)(2)(B)) is amended by adding at the end the following new clause:

''(v) marriage and family therapist services (as defined in section 1861(jjj)(1)) and mental health counselor services (as defined in section 1861(jjj)(3));''.

(4) AMOUNT OF PAYMENT.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395*l*(a)(1)) is amended—

(A) by striking ''and (BB)'' and inserting ''(BB)''; and

(B) by inserting before the semicolon at the end the following: '', and (CC) with respect

to marriage and family therapist services and mental health counselor services under section 1861(s)(2)(HH), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for payment of a psychologist under subparagraph (L)''.

(5) EXCLUSION OF MARRIAGE AND FAMILY THERAPIST SERVICES AND MENTAL HEALTH COUNSELOR SERVICES FROM SKILLED NURSING FACILITY PROSPECTIVE PAYMENT SYSTEM.—Section 1888(e)(2)(A)(ii) of the Social Security Act (42 U.S.C. 1395yy(e)(2)(A)(ii)) is amended by inserting ''marriage and family therapist services (as defined in section 1861(jjj)(1)), mental health counselor services (as defined in section 1861(jjj)(3)),'' after ''qualified psychologist services,''.

(6) INCLUSION OF MARRIAGE AND FAMILY THERAPISTS AND MENTAL HEALTH COUNSELORS AS PRACTITIONERS FOR ASSIGNMENT OF CLAIMS.—Section 1842(b)(18)(C) of the Social Security Act (42 U.S.C. 1395u(b)(18)(C)) is amended by adding at the end the following new clauses:

''(vii) A marriage and family therapist (as defined in section 1861(jjj)(2)).

''(viii) A mental health counselor (as defined in section 1861(jjj)(4)).''.

(b) COVERAGE OF CERTAIN MENTAL HEALTH SERVICES PROVIDED IN CERTAIN SETTINGS.—

(1) RURAL HEALTH CLINICS AND FEDERALLY QUALIFIED HEALTH CENTERS.—Section 1861(aa)(1)(B) of the Social Security Act (42 U.S.C. 1395x(aa)(1)(B)) is amended by striking ''or by a clinical social worker (as defined in subsection (hh)(1))'' and inserting '', by a clinical social worker (as defined in subsection (hh)(1)), by a marriage and family therapist (as defined in subsection (jjj)(2)), or by a mental health counselor (as defined in subsection (jjj)(4))''.

(2) HOSPICE PROGRAMS.—Section 1861(dd)(2)(B)(i)(III) of the Social Security Act (42 U.S.C. 1395x(dd)(2)(B)(i)(III)) is amended by inserting '', marriage and family therapist, or mental health counselor'' after ''social worker''.

(c) AUTHORIZATION OF MARRIAGE AND FAMILY THERAPISTS AND MENTAL HEALTH COUNSELORS TO DEVELOP DISCHARGE PLANS FOR POST-HOSPITAL SERVICES.—Section 1861(ee)(2)(G) of the Social Security Act (42 U.S.C. 1395x(ee)(2)(G)) is amended by inserting '', including a marriage and family therapist and a mental

health counselor who meets qualification standards established by the Secretary'' before the period at the end.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to services furnished on or after January 1, 2019.

SEC. 7. SYNTHETICS TRAFFICKING AND OVERDOSE PREVENTION.

(a) FORMAL ENTRY REQUIREMENTS—POSTAL SERVICE AS CONSIGNEE.—Subparagraph (B) of section 484(a)(2) of the Tariff Act of 1930 (19 U.S.C. 1484(a)(2)(B)) is amended to read as follows:

''(B)(i) When an entry of merchandise is made under this section, the required documentation or information shall be filed or electronically transmitted—

''(I) by the owner or purchaser of the merchandise; or

''(II) when appropriately designated by the owner, purchaser, or consignee of the merchandise, by a person holding a valid license under section 641.

''(ii) The Postmaster General shall be deemed the consignee for merchandise, as defined by section 498(c), imported through the mail, and the Postmaster General shall, at the Postmaster General's

sole expense, designate a person holding a valid license under section 641 to file the required documentation or information or ensure that the owner or purchaser of the merchandise or a person holding a valid license under section 641 that is designated by the owner or purchaser files the required documentation or information.

''(iii) When a consignee declares on entry that he or she is the owner or purchaser of merchandise, U.S. Customs and Border Protection may, without liability, accept the declaration.

''(iv) For the purposes of this Act, the importer of record must be one of the parties who is eligible to file the documentation or information required by this section.''.

(b) INFORMAL ENTRIES.—Section 498 of the Tariff Act of 1930 (19 U.S.C. 1498) is amended by adding at the end the following:

''(c) APPLICATION TO POSTAL SHIPMENTS.—

''(1) DEFINITIONS.—In this subsection:

''(A) DOCUMENT.—The term 'document' means a piece of written, drawn, printed, or digital information, excluding objects of merchandise, that—

''(i) is conveyed in an envelope that is less than or equal to 165 millimeters in width, 245 millimeters in length, and 5 millimeters in depth; and

''(ii) weighs 100 grams or less when conveyed.

''(B) MERCHANDISE.—The term 'merchandise' has the same meaning as that term is defined in section 401 but does not include a document.

''(2) REQUIREMENT.—Notwithstanding any other provision of law, for merchandise meeting the requirements of subsection (a), the Postmaster General shall comply with the entry requirements of section 484.

''(3) REGULATIONS.—Any regulation issued pursuant to this subsection shall apply identical entry procedures for merchandise imported through the mail as are applied for merchandise imported via a private carrier.''.

(c) DE MINIMIS SHIPMENTS.—Section 321 of the Tariff Act of 1930 (19 U.S.C. 1321) is amended by adding at the end the following:

''(c)(1) For imported articles that qualify for the administrative exemption under subsection (a)(2) and that

arrive at international mail facilities in the United States, the Postmaster General shall be deemed the consignee for such articles that are considered merchandise, as the term is defined in section 498(c).

''(2) In addition to the parties that are authorized to comply with the entry requirements of sections 498 and 484, the Postmaster General, as a consignee, may, using reasonable care, enter such merchandise that qualifies for the administrative exemption under subsection (a)(2).''.

(d) CUSTOMS FEES.—

(1) IN GENERAL.—Paragraph (6) of section 13031(a) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (19 U.S.C. 58c(a)(6)) is amended to read as follows:

''(6)(A) For the arrival of shipments of merchandise (as the term is defined in section 498(c) of the Trade Act of 1930) or any other item that is valued at $2,000 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 498 of the Tariff Act of 1930 (19 U.S.C. 1498) and subject to adjustment under subsection (l)) arriving at an international mail facility:

"(i) $1 per individual airway bill or bill of lading (subject to adjustment under subsection (l)); or

"(ii) if such merchandise is formally entered, the fee provided for in paragraph (9), if applicable.

"(B) Notwithstanding section 451 of the Tariff Act of 1930 (19 U.S.C. 1451), the payment required by subparagraph (A) shall be the only payment required for reimbursement of U.S. Customs and Border Protection in connection with the processing of an individual airway bill or bill of lading in accordance with such subparagraph and for providing services at international mail facilities, except that U.S. Customs and Border Protection may require such facilities to cover expenses of the agency for adequate office space, equipment, furnishings, supplies, and security.

"(C) The payment required by subparagraphs (A) and (B) shall be paid on a quarterly basis by the Postmaster General in accordance with regulations prescribed by the Secretary of the Treasury. The payments shall be allocated as follows:

"(i) 50 percent of the amount of payments received in this paragraph shall, in accordance

with section 524 of the Tariff Act of 1930 (19 U.S.C. 1524), be deposited in the Customs User Fee Account and shall be used to directly reimburse each appropriation for the amount paid out of that appropriation for the costs incurred in providing services to international mail facilities. Amounts deposited in accordance with the preceding sentence shall be available until expended for the provision of customs services to international mail facilities.

''(ii) Notwithstanding section 524 of the Tariff Act of 1930 (19 U.S.C. 1524), 50 percent of the amount of payments received under this paragraph shall be paid to the Secretary of the Treasury, which is in lieu of the payment of fees under paragraph (10).''.

(2) TECHNICAL AMENDMENTS.—Paragraph (10) of section 13031(a) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (19 U.S.C. 58c(a)(10)) is amended—

(A) by striking ''or'' in subparagraph (B);

(B) by striking the period at the end of subparagraph (C)(iii) and inserting a comma and ''or'';

(C) by inserting after subparagraph (C)(iii) the following:

''(D) an international mail facility.''; and

(D) in the undesignated material at the end by striking the period and inserting ''or referred to in subparagraph (D) see paragraph (6).''.

(e) MANDATORY ADVANCED ELECTRONIC INFORMATION FOR POSTAL SHIPMENTS.—Subparagraph (K) of section 343(a)(3) of the Trade Act of 2002 (Public Law 107–210; 19 U.S.C. 2071 note) is amended to read as follows:

''(K) The Secretary shall require the Postmaster General to transmit or to ensure the transmission of the information required in paragraphs (1) and (2) to U.S. Customs and Border Protection for all shipments by the United States Postal Service which includes shipments that the United States Postal Service receives from foreign postal operators (shipments from foreign postal operators may be transported by private carriers). All regulations issued pursuant to this provision are required to impose the same information requirements

on the United States Postal Service and private carriers.''.

(f) MANIFEST PENALTIES APPLIED TO THE UNITED STATES POSTAL SERVICE.—

(1) PENALTIES FOR VIOLATIONS OF THE ARRIVAL, REPORTING, ENTRY, AND CLEARANCE REQUIREMENTS.—Section 436 of the Tariff Act of 1930 (19 U.S.C. 1436) is amended by adding at the end the following new subsection:

''(e) CIVIL PENALTIES ARISING FROM VIOLATIONS FOR POSTAL SHIPMENTS.—With respect to civil penalties provided for in subsections (b) and (d), the Postmaster General shall be liable for the penalty if the violation was caused by a foreign postal operator or the United States Postal Service.''.

(2) PENALTIES FOR FALSITY OR LACK OF MANIFEST.—Section 584 of the Tariff Act of 1930 (19 U.S.C. 1584) is amended by adding at the end the following new subsection:

''(c) PERSON DIRECTLY OR INDIRECTLY RESPONSIBLE SHALL INCLUDE THE POSTMASTER GENERAL.—For purposes of subsection (a), the Postmaster General may be the person directly or indirectly responsible for a discrepancy if the discrepancy is the result of—

''(1) an omission by a foreign postal operator or the United States Postal Service; or

''(2) false information regarding the shipment that was provided to the carrier by a foreign postal operator or the United States Postal Service.''.

(g) LIMITATION ON INTERNATIONAL POSTAL ARRANGEMENTS.—

(1) EXISTING AGREEMENTS.—

(A) IN GENERAL.—In the event that any provision in this section is found to be in violation of obligations of the United States under the Universal Postal Union, the Secretary of State shall negotiate to amend the relevant provisions of the agreement so that the United States is no longer in violation of the agreement.

(B) CONSTRUCTION.—Nothing in this subsection may be construed to require or permit any delay in the implementation of this section.

(2) FUTURE AGREEMENTS.—The Secretary of State may not conclude any international postal arrangement pursuant to the authority set out in section 407 of title 39, United States Code, that is inconsistent with this section or any amendment made by this section.

(h) APPLICATION OF OTHER CUSTOMS LAWS.—

(1) IN GENERAL.—U.S. Customs and Border Protection shall ensure that all merchandise, as that term is defined in subsection (c) of section 498 of the Tariff Act of 1930 (19 U.S.C. 1498), imported to the United States through the mail shall be subject to the same import procedures, legal restrictions, and certifications as merchandise imported by private carriers.

(2) REGULATIONS.—The Secretary of the Treasury shall issue regulations pursuant to this section to ensure that merchandise imported through the mail is in accordance with Federal law.

(i) COST RECOUPMENT.—The Postmaster General shall ensure that all costs associated with complying with this section, as well as all penalties assessed against the Postmaster General, are charged directly to foreign shippers, foreign postal operators, or United States ultimate consignees.

(j) EFFECTIVE DATE; REGULATIONS.—

(1) EFFECTIVE DATE.—This section shall become effective upon the date of the enactment of this Act.

(2) REGULATIONS.—Not later than 1 year after the date of the enactment of this Act, the Secretary

shall prescribe all regulations required under this section.

SEC. 8. STOP THE IMPORTATION AND TRAFFICKING OF SYNTHETIC ANALOGUES.

(a) ESTABLISHMENT OF SCHEDULE A.—Section 202 of the Controlled Substances Act (21 U.S.C. 812) is amended—

(1) in subsection (a), by striking ''five schedules of controlled substances, to be known as schedules I, II, III, IV, and V'' and inserting ''six schedules of controlled substances, to be known as schedules I, II, III, IV, V, and A'';

(2) in subsection (b), by adding at the end the following:

''(6) SCHEDULE A.—

''(A) IN GENERAL.—The drug or substance—

''(i) has—

''(I) a chemical structure that is substantially similar to the chemical structure of a controlled substance in schedule I, II, III, IV, or V; and

''(II) an actual or predicted stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant,

depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I, II, III, IV, or V; and

"(ii) is not—

"(I) listed or otherwise included in any other schedule in this section or by regulation of the Attorney General; and

"(II) with respect to a particular person, subject to an exemption that is in effect for investigational use, for that person, under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to the extent conduct with respect to such substance is pursuant to such exemption.

"(B) PREDICTED STIMULANT, DEPRESSANT, OR HALLUCINOGENIC EFFECT.—For purpose of this paragraph, a predicted stimulant, depressant, or hallucinogenic effect on the central nervous system may be based on—

"(i) the chemical structure, structure activity relationships, binding receptor assays, or other relevant scientific information about the substance;

"(ii)(I) the current or relative potential for abuse of the substance; and

''(II) the clandestine importation, manufacture, or distribution, or diversion from legitimate channels, of the substance; or

''(iii) the capacity of the substance to cause a state of dependence, including physical or psychological dependence that is similar to or greater than that of a controlled substance in schedule I, II, III, IV, or V.''; and

(3) in subsection (c)—

(A) in the matter preceding schedule I, by striking ''IV, and V'' and inserting ''IV, V, and A''; and

(B) by adding at the end the following:

''SCHEDULE A

''(a) Unless specifically excepted or unless listed in another schedule, any of the following substances, as scheduled in accordance with section 201(k)(5):

''(1) 4-fluoroisobutyryl fentanyl.

''(2) Valeryl fentanyl.

''(3) 4-methoxybutyryl fentanyl.

''(4) 4-methylphenethyl acetyl fentanyl.

''(5) 3-furanyl fentanyl.

''(6) Ortho-fluorofentanyl.

''(7) Tetrahydrofuranyl fentanyl.

''(8) Ocfentanil.

''(9) 4-fluorobutyryl fentanyl.

''(10) Methoxyacetyl fentanyl.

''(11) Meta-fluorofentanyl.

''(12) Isobutyryl fentanyl.

''(13) Acryl fentanyl.''.

(b) TEMPORARY AND PERMANENT SCHEDULING OF SCHEDULE A SUBSTANCES.—Section 201 of the Controlled Substances Act (21 U.S.C. 811) is amended by adding at the end the following:

''(k) TEMPORARY AND PERMANENT SCHEDULING OF SCHEDULE A SUBSTANCES.—

''(1) The Attorney General may issue a temporary order adding a drug or substance to schedule A if the Attorney General finds that—

''(A) the drug or other substance satisfies the criteria for being considered a schedule A substance; and

''(B) adding such drug or substance to schedule A will assist in preventing abuse or misuse of the drug or other substance.

''(2) A temporary scheduling order issued under paragraph (1) shall not take effect until 30 days after the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued. The temporary

scheduling order shall expire not later than 5 years after the date it becomes effective, except that the Attorney General may, during the pendency of proceedings under paragraph (5), extend the temporary scheduling order for up to 180 days.

''(3) A temporary scheduling order issued under paragraph (1) shall be vacated upon the issuance of a permanent order issued under paragraph (5) with regard to the same substance, or upon the subsequent issuance of any scheduling order under this section.

''(4) A temporary scheduling order issued under paragraph (1) shall not be subject to judicial review.

''(5) The Attorney General may, by rule, issue a permanent order adding a drug or other substance to schedule A if such drug or substance satisfies the criteria for being considered a schedule A substance. Such rulemaking may be commenced simultaneously with the issuance of the temporary scheduling order issued under paragraph (1) with regard to the same substance.

''(6) Before initiating proceedings under paragraph (1) or (5), the Attorney General shall transmit notice of an order proposed to be issued to the Secretary of Health and Human Services. In issuing

an order under paragraph (1) or (5), the Attorney General shall take into consideration any comments submitted by the Secretary of Health and Human Services in response to a notice transmitted pursuant to this paragraph.

''(7) On the date of the publication of a notice in the Federal Register pursuant to paragraph (2), the Attorney General shall transmit the same notice to Congress. The temporary scheduling order shall take effect according to paragraph (2), except that the temporary scheduling order may be disapproved by Act of Congress within 180 days from the date of publication of the notice in the Federal Register.''.

(c) PENALTIES.—

(1) CONTROLLED SUBSTANCES ACT.—The Controlled Substances Act (21 U.S.C. 801 et seq.) is amended—

(A) in section 401(b)(1) (21 U.S.C. 841(b)(1)), by adding at the end the following:

''(F)(i) In the case of any controlled substance in schedule A, such person shall be sentenced to a term of imprisonment of not more than 10 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of

not more than 15 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $500,000 if the defendant is an individual or $2,500,000 if the defendant is other than an individual, or both.

''(ii) If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not more than 30 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $1,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both.

''(iii) Any sentence imposing a term of imprisonment under this subparagraph shall, in the absence of such a prior conviction, impose a term of supervised release of not less than 2 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of not less than 4 years in addition to such term of imprisonment.'';

(B) in section 403(a) (21 U.S.C. 843(a))—

(i) in paragraph (8), by striking ''or'' at the end;

(ii) in paragraph (9), by striking the period at the end and inserting ''; or''; and

(iii) by inserting after paragraph (9) the following:

''(10) to export a substance in violation of the controlled substance laws of the country to which the substance is exported.''; and

(C) in section 404 (21 U.S.C. 844), by inserting after subsection (a) the following:

''(b) A person shall not be subject to a criminal or civil penalty under this title or under any other Federal law solely for possession of a schedule A controlled substance.''.

(2) CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT.—Section 1010(b) of the Controlled Substances Import and Export Act (21 U.S.C. 960(b)) is amended by adding at the end the following:

''(8) In the case of a violation under subsection (a) involving a controlled substance in schedule A, the person committing such violation shall be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such sub-

stance shall be sentenced to a term of imprisonment of not more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $1,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 30 years and if death or serious bodily injury results from the use of such substance shall be sentenced to not more than life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $2,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18, United States Code, any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of not less than 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of not less than 6 years in addition to such term of imprisonment. Notwithstanding the prior sentence, and notwithstanding any other provision of law, the court shall not place on

probation or suspend the sentence of any person sentenced under the provisions of this paragraph which provide for a mandatory term of imprisonment if death or serious bodily injury results.''.

(d) FALSE LABELING OF SCHEDULE A CONTROLLED SUBSTANCES.—

(1) IN GENERAL.—Section 305 of the Controlled Substances Act (21 U.S.C. 825) is amended by adding at the end the following:

''(f) FALSE LABELING OF SCHEDULE A CONTROLLED SUBSTANCES.—

''(1) It shall be unlawful to import, export, manufacture, distribute, dispense, or possess with intent to manufacture, distribute, or dispense, a schedule A substance or product containing a schedule A substance, unless the substance or product bears a label clearly identifying a schedule A substance or product containing a schedule A substance by the nomenclature used by the International Union of Pure and Applied Chemistry (IUPAC).

''(2)(A) A product described in subparagraph (B) is exempt from the International Union of Pure and Applied Chemistry nomenclature requirement of this subsection if such product is labeled in the man-

ner required under the Federal Food, Drug, and Cosmetic Act.

''(B) A product is described in this subparagraph if the product—

''(i) is the subject of an approved application as described in section 505(b) or (j) of the Federal Food, Drug, and Cosmetic Act; or

''(ii) is exempt from the provisions of section 505 of such Act relating to new drugs because—

''(I) it is intended solely for investigational use as described in section 505(i) of such Act; and

''(II) such product is being used exclusively for purposes of a clinical trial that is the subject of an effective investigational new drug application.''.

(2) PENALTIES.—Section 402 of the Controlled Substances Act (21 U.S.C. 842) is amended—

(A) in subsection (a)(16), by inserting ''or subsection (f)'' after ''subsection (e)''; and

(B) in subsection (c)(1)(D), by inserting ''or a schedule A substance'' after ''anabolic steroid''.

(e) REGISTRATION REQUIREMENTS FOR HANDLERS OF SCHEDULE A SUBSTANCES.—

(1) CONTROLLED SUBSTANCES ACT.—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

''(k)(1) The Attorney General shall register an applicant to manufacture schedule A substances if—

''(A) the applicant demonstrates that the schedule A substances will be used for research, analytical, or industrial purposes approved by the Attorney General; and

''(B) the Attorney General determines that such registration is consistent with the public interest and with the United States obligations under international treaties, conventions, or protocols in effect on the date of enactment of this subsection.

''(2) In determining the public interest under paragraph (1)(B), the Attorney General shall consider—

''(A) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule A compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments

which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

''(B) compliance with applicable State and local law;

''(C) promotion of technical advances in the art of manufacturing substances described in subparagraph (A) and the development of new substances;

''(D) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of substances described in paragraph (A);

''(E) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

''(F) such other factors as may be relevant to and consistent with the public health and safety.

''(3) If an applicant is registered to manufacture controlled substances in schedule I or II under subsection (a), the applicant shall not be required to apply for a separate registration under this subsection.

''(l)(1) The Attorney General shall register an applicant to distribute schedule A substances—

''(A) if the applicant demonstrates that the schedule A substances will be used for research, analytical, or industrial purposes approved by the Attorney General; and

''(B) unless the Attorney General determines that the issuance of such registration is inconsistent with the public interest.

''(2) In determining the public interest under paragraph (1)(B), the Attorney General shall consider—

''(A) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

''(B) compliance with applicable State and local law;

''(C) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of substances described in subparagraph (A);

''(D) past experience in the distribution of controlled substances; and

''(E) such other factors as may be relevant to and consistent with the public health and safety.

''(3) If an applicant is registered to distribute a controlled substance in schedule I or II under subsection (b),

the applicant shall not be required to apply for a separate registration under this subsection.

''(m)(1) Not later than 90 days after the date on which a substance is placed in schedule A, any practitioner who was engaged in research on the substance before the placement of the substance in schedule A and any manufacturer or distributor who was handling the substance before the placement of the substance in schedule A shall register with the Attorney General.

''(2)(A) Not later than 60 days after the date on which the Attorney General receives an application for registration to conduct research on a schedule A substance, the Attorney General shall—

''(i) grant, or initiate proceedings under section 304(c) to deny, the application; or

''(ii) request supplemental information from the applicant.

''(B) Not later than 30 days after the date on which the Attorney General receives supplemental information requested under subparagraph (A)(ii) in connection with an application described in subparagraph (A), the Attorney General shall grant or deny the application.

''(n)(1) The Attorney General shall register a scientific investigator or a qualified research institution to conduct research with controlled substances in schedule A

in accordance with this subsection. In evaluating applications for such registration, the Attorney General shall apply the criteria set forth in subsection (f) of this section that apply to practitioners seeking a registration to conduct research with a schedule I controlled substance, except that the applicant shall not be required to submit a research protocol.

''(2) If the applicant is not currently registered under subsection (f) to conduct research with a schedule I controlled substance, the Attorney General shall refer the application to the Secretary, who shall determine whether the applicant will be engaged in bona fide research and is qualified to conduct such research.

''(3) If the applicant is currently registered under subsection (f) to conduct research with a schedule I controlled substance, the applicant will be considered qualified to conduct research with controlled substances in schedule A and the Attorney General shall modify the applicant's registration to include schedule A controlled substances in accordance with this paragraph. The applicant shall notify the Attorney General of his intent to conduct research with a controlled substance in schedule A. Upon receiving such notification, the Attorney General shall modify the practitioner's existing registration to authorize research with schedule A controlled substances, unless the Attorney

General determines that the registration modification would be inconsistent with the public interest based on the criteria of subsection (f).

''(4) Registrations issued under this subsection to a qualified research institution will apply to all agents and employees of that institution acting within the scope of their professional practice.

''(5) At least thirty days prior to conducting any research with a controlled substance in schedule A, the registrant shall provide the Attorney General with written notification of the following:

''(A) The name of and drug code for each substance.

''(B) The name of each individual with access to each substance.

''(C) The amount of each substance.

''(D) Other similar information the Attorney General may require.

''(6) The quantity of a schedule A controlled substance possessed by a person registered under this subsection shall be appropriate for the research being conducted, subject to the additional limitations set forth in this paragraph. To reduce the risk of diversion, the Attorney General may establish limitations on the quantity of schedule A controlled substances that may be manufac-

tured or possessed for purposes of research under this subsection and shall publish such limitations on the website of the Drug Enforcement Administration. A person registered under this subsection may, based on legitimate research needs, apply to the Attorney General to manufacture or possess an amount greater than that so specified by the Attorney General. The Attorney General shall specify the manner in which such applications shall be submitted. The Attorney General shall act on an application filed under this subparagraph within 30 days of receipt of such application. If the Attorney General fails to act within 30 days, the registrant shall be allowed to manufacture and possess up to the amount requested. The Attorney General shall have the authority to reverse the increase for cause.

''(7) The Attorney General shall by regulation specify the manner in which applications for registration under this subsection shall be submitted.

''(8) Registrants authorized under this subsection may manufacture and possess schedule A controlled substances up to the approved amounts only for use in their own research setting or institution. Manufacturing for use in any other setting or institution shall require a manufacturer's registration under section 303(a).''.

(2) CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT.—Section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958) is amended by adding at the end the following:

''(j)(1) The Attorney General shall register an applicant to import or export a schedule A substance if—

''(A) the applicant demonstrates that the schedule A substances will be used for research, analytical, or industrial purposes approved by the Attorney General; and

''(B) the Attorney General determines that such registration is consistent with the public interest and with the United States obligations under international treaties, conventions, or protocols in effect on the date of enactment of this subsection.

''(2) In determining the public interest under paragraph (1)(B), the Attorney General shall consider the factors described in subparagraphs (A) through (F) of section 303(k)(2).

''(3) If an applicant is registered to import or export a controlled substance in schedule I or II under subsection (a), the applicant shall not be required to apply for a separate registration under this subsection.''.

(f) ADDITIONAL CONFORMING AMENDMENTS.—

(1) CONTROLLED SUBSTANCES ACT.—The Controlled Substances Act (21 U.S.C. 801 et seq.) is amended—

(A) in section 303(c) (21 U.S.C. 823(c))—

(i) by striking ''subsections (a) and (b)'' and inserting ''subsection (a), (b), (k), or (l)''; and

(ii) by striking ''schedule I or II'' and inserting ''schedule I, II, or A'';

(B) in section 306 (21 U.S.C. 826)—

(i) in subsection (a), in the first sentence, by striking ''schedules I and II'' and inserting ''schedules I, II, and A'';

(ii) in subsection (b), in the second sentence, by striking ''schedule I or II'' and inserting ''schedule I, II, or A'';

(iii) in subsection (c), in the first sentence, by striking ''schedules I and II'' and inserting ''schedules I, II, and A'';

(iv) in subsection (d), in the first sentence, by striking ''schedule I or II'' and inserting ''schedule I, II, or A'';

(v) in subsection (e), in the first sentence, by striking ''schedule I or II'' and inserting ''schedule I, II, or A''; and

(vi) in subsection (f), in the first sentence, by striking ''schedules I and II'' and inserting ''schedules I, II, and A'';

(C) in section 308(a) (21 U.S.C. 828(a)), by striking ''schedule I or II'' and inserting ''schedule I, II, or A'';

(D) in section 402(b) (21 U.S.C. 842(b)), in the matter preceding paragraph (1), by striking ''schedule I or II'' and inserting ''schedule I, II, or A'';

(E) in section 403(a)(1) (21 U.S.C. 843(a)(1)), by striking ''schedule I or II'' and inserting ''schedule I, II, or A''; and

(F) in section 511(f) (21 U.S.C. 881(f)), by striking ''schedule I or II'' each place it appears and inserting ''schedule I, II, or A''.

(2) CONTROLLED SUBSTANCES IMPORT EXPORT ACT.—The Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.) is amended—

(A) in section 1002(a) (21 U.S.C. 952(a))—

(i) in the matter preceding paragraph (1), by striking ''schedule I or II'' and inserting ''schedule I, II, or A''; and

(ii) in paragraph (2), by striking ''schedule I or II'' and inserting ''schedule I, II, or A'';

(B) in section 1003 (21 U.S.C. 953)—

(i) in subsection (c), in the matter preceding paragraph (1), by striking ''schedule I or II'' and inserting ''schedule I, II, or A''; and

(ii) in subsection (d), by striking ''schedule I or II'' and inserting ''schedule I, II, or A'';

(C) in section 1004(1) (21 U.S.C. 954(1)), by striking ''schedule I'' and inserting ''schedule I or A'';

(D) in section 1005 (21 U.S.C. 955), by striking ''schedule I or II'' and inserting ''schedule I, II, or A''; and

(E) in section 1009(a) (21 U.S.C. 959(a)), by striking ''schedule I or II'' and inserting ''schedule I, II, or A''.

(g) CONTROLLED SUBSTANCE ANALOGUES.—Section 102 of the Controlled Substances Act (21 U.S.C. 802) is amended—

(1) in paragraph (6), by striking ''or V'' and inserting ''V, or A'';

(2) in paragraph (14)—

(A) by striking ''schedule I(c) and'' and inserting ''schedule I(c), schedule A, and''; and

(B) by striking ''schedule I(c),'' and inserting ''schedule I(c) and schedule A,''; and

(3) in paragraph (32)(A), by striking ''(32)(A)'' and all that follows through clause (iii) and inserting the following:

''(32)(A) Except as provided in subparagraph (C), the term 'controlled substance analogue' means a substance whose chemical structure is substantially similar to the chemical structure of a controlled substance in schedule I or II—

''(i) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or

''(ii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallu-

cinogenic effect on the central nervous system of a controlled substance in schedule I or II.''.

(h) AMENDMENT TO THE SENTENCING GUIDELINES.—Section 2D1.1 of the Federal Sentencing Guidelines is amended, in Application Note 6 (Analogues and Controlled Substances Not Referenced in this Guideline) of the Commentary, by striking ''In determining the most closely related controlled substance, the court shall, to the extent practicable, consider the following:'' and inserting the following: ''In determining the most closely related controlled substance and the applicable guideline or drug equivalence, the court shall—

''(A) if Attorney General has provided guidance on the appropriate sentencing equivalency or ratio to a controlled substance that is referenced in the guidelines through publication in the Federal Register (whether such guidance is included in or separate from any notice of proposed temporary or permanent scheduling of such substance under section 201 of the Controlled Substances Act (21 U.S.C. 811)), apply any such sentencing equivalency or ratio; and

''(B) in the absence of guidance with respect to a substance or group of substances as described in paragraph (A), use equivalencies

for the following structural classes of substances as if they were included on the Drug Equivalency Tables:

''Drug Class	Marihuana Equivalency of 1 gm of subject substance
Synthetic Opioids	1 gm = 10 kg
Synthetic Cannabinoids	1 gm = 167 gm
Synthetic Cathinones	1 gm = 380 gm
Tryptamine	1 gm = 80 gm
Phenethylamines	1 gm = 2.5 kg
Piperazines	1 gm = 2 kg
Benzofurans	1 gm = 500 gm
Arylcyclohexylamines (PCP-like substances)	1 gm = 1 kg
Methylphenidate analogs	1 gm = 100 gm
Benzodiazepines	1 'unit' (as defined in Note (F) to the Drug Quantity Table in 2D1.1) = 0.0625 gm

In the case of a substance for which paragraphs (A) and (B) above are not applicable, the court shall determine an equivalency or ratio by considering the following factors, to the extent practicable:''.

(i) RULES OF CONSTRUCTION.—Nothing in this section, or the amendments made by this section, may be construed to limit—

(1) the prosecution of offenses involving controlled substance analogues under the Controlled Substances Act (21 U.S.C. 801 et seq.); or

(2) the authority of the Attorney General to temporarily or permanently schedule, reschedule, or decontrol controlled substances under provisions of section 201 of the Controlled Substances Act (21

U.S.C. 811) that are in effect on the day before the date of enactment of this Act.

(j) STUDY BY COMPTROLLER GENERAL.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall complete a study and submit a report to the Committees on the Judiciary of the House of Representatives and of the Senate regarding the costs associated with the amendments made by subsection (c), including—

(1) the annual amounts expended by Federal agencies in carrying out the amendments;

(2) the costs associated with arrests, trials, convictions, imprisonment, or imposition of other sanctions in accordance with the amendments; and

(3) the impact (including the fiscal impact) of the amendments on existing correctional facilities and the likelihood that those amendments will create a need for additional capacity for housing prisoners.

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