THE COMPREHENSIVE ADDICTION RESOURCES EMERGENCY (CARE) ACT
Section-By-Section

***Purpose**: The purpose of the Act is to provide emergency assistance to States, territories, Tribal nations, and local areas that are disproportionately affected by substance use disorder, including but not limited to the use of opioids and stimulants, and to make financial assistance available to provide for the development, organization, coordination, and operation of more effective and cost-efficient systems for the delivery of services to individuals with substance use disorder and their families.*

Section 3: AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT: This section amends the Public Health Service Act to add a new title, "Substance Use Resources."

SUBTITLE A (Grants to Local Areas)

SECTION 3401: ESTABLISHMENT OF A PROGRAM OF GRANTS

This section establishes a program, administered by the Secretary of the Department of Health and Human Services (HHS), to award grants to local areas for the purpose of addressing substance use within those areas.

Eligibility for Local Area Formula Grants (Sec. 3401(b))
Local areas eligible for formula grants are:

1. Counties and independent cities with a rate of drug overdose deaths per 100,000 people not less than the rate of such deaths for the county at the 67th percentile of all counties; or

2. Counties and independent cities that can demonstrate that the number of drug overdose deaths during the most recent three-year period was not less than the number of deaths for the county that ranked at the 90th percentile of all counties; or

3. Counties that encompass an underserved area (defined as a health professional shortage area or a medically underserved area) that can demonstrate a high burden of both fatal and non-fatal drug overdoses in a manner determined by the Secretary.

Treatment of contiguous counties: Any eligible county that is contiguous to one or more eligible counties form a group of counties that shall be considered as a single eligible county and the group of counties shall submit one grant application and form a joint planning council. Contiguous counties must also establish an administrative mechanism to allocate funds and services based on the number of drug overdoses in each of the counties, the severity of the need for services, and the health and support service personnel needs of each county.

Treatment of cities and counties within multiple contiguous counties: Any city that is within an eligible county or any county or group of counties within a group of contiguous counties shall be eligible to receive its own grant—independent from the broader group of contiguous counties—if

it has a population of at least 50,000 residents, submits its own application, and establishes its own planning council. A local area that does not have at least 50,000 residents can apply for a waiver if it can demonstrate that the needs of its population are distinct, that addressing substance use in the area would be best served by the formation of an independent planning council, and that the entity has the capacity to administer grant funding.

Treatment of political subdivisions: The Secretary shall determine eligible local political subdivisions in States that do not have a local county system of government.

Lack of Data: Whenever the data required to demonstrate eligibility for grants are not available, the Secretary shall establish eligibility criteria.

Study: The Comptroller General shall conduct a study to determine whether the data being used to assess local areas' eligibility for formula grant funding provide the most precise measure of local areas' need for such funding, or whether additional data would provide more precise measures of substance use and addiction prevalence.

Administration of Local Grants (Sec. 3401(c))
Grants shall be awarded to the chief elected official of the eligible local area receiving the funds. In the case of multiple contiguous counties submitting one application for funds, grant funds will be administered by the chief elected official of the county identified in the application submitted by the group of counties. Multiple contiguous counties may elect to have the state administer their grant funds.

SECTION 3402: PLANNING COUNCIL FOR LOCAL AREA GRANTS

Establishment of the Planning Council (Sec. 3402(a))
Eligible local areas must establish a substance use disorder services planning council to receive grant funds. The membership of local areas' planning councils must be representative of the population with substance use disorder and include individuals with substance use disorder, individuals who use drugs, and individuals in recovery from substance use disorders. Further to the planning councils must include (to the maximum extent possible): representatives of health care providers (including federal qualified health centers, rural health clinics, Indian health programs, urban Indian organizations, Native Hawaiian organizations, and facilities operated by the Department of Veterans Affairs); community-based health, harm reduction, or addiction service organizations, including representatives of Drug Free Communities Coalition grantees; social service providers; mental health care providers; local public health agencies; State and local governments (including the State Medicaid agency and the Single State Agency for Substance Abuse Services); non-elected community leaders; substance use disorder treatment providers, including physician addiction specialists; members of Federally-recognized Indian tribes; Urban Indians; historically underserved groups and sub-populations; individuals who were formerly incarcerated; organizations serving individuals who are incarcerated or in pre-trial detention; Federal agencies; organizations that provide services to youth at risk of substance use; medical examiners or coroner; labor unions and the workplace community; fire departments and emergency medical services; the LGBTQ community; and certified or accredited addiction recovery community organizations.

Method of Providing for the Planning Council (Sec. 3402(b))
The planning council may be created for the purposes of this grant program, or an existing entity with demonstrated experience in the provision of health and support services to individuals with substance use disorder may be designated to serve as the council.

Other situations may arise:

- *Non-contiguous local areas:* The Secretary must establish a process permitting eligible local areas that are not contiguous with any other eligible local areas to form a joint planning council with other eligible local areas as long as such areas are located in geographical proximity to each other and submit a joint application.
- *Across state lines:* Eligible local areas can form a joint planning council with other eligible local areas across State lines if such areas are in geographical proximity and if they establish an intergovernmental agreement to allow the administration of a grant across State lines.

Membership of the Planning Council (Sec. 3402(c))
Members will be nominated and selected through an open process and will elect from among their membership a chair and vice chair. The council must include at least one representative from Indian tribes located within any eligible local area, at least one individual with a history of substance use disorder, at least one representative of a nonprofit substance use disorder service provider, at least one representative from an urban Indian organization, at least one physician addiction specialist, at least one representative of an organization providing harm reduction services, and, when applicable, at least one representative from a Native Hawaiian organization. Members cannot serve more than three consecutive years on a planning council.

Membership Terms of the Planning Council (Sec. 3402(d))
Members of the planning council can serve additional terms if they are nominated and selected through the open process through which all planning council members are selected.

Duties of the Planning Council (Sec. 3402(e))
The planning council shall:

- Establish priorities for the allocation of grant funds within the local area that emphasize reducing drug use rates, overdoses, substance use disorder, and health conditions associated with drug use such as human immunodeficiency virus, hepatitis B, and hepatitis C through evidence-based interventions in both community and criminal justice settings;
- Ensure that grant funds will advance any existing state or local plan regarding the provision of substance use disorder treatments. In the absence of a state or local plan, the planning council must work with local public health agencies to develop a comprehensive plan for the organization and delivery of substance use disorder treatment services;
- Assess the efficiency of the administrative mechanism in allocating these funds, and work with local public health agencies to determine the size, demographics, and needs of the population of individuals with substance use disorder; determine disparities in access to services among affected subpopulations and historically underserved communities;

establish methods for obtaining input on community needs and priorities; and coordinate with Federal grantees providing substance use-related services in the area; and

- Annually assess the effectiveness of the services supported by grants on substance use and recovery.

Conflicts of Interest (Sec. 3402(f))
The planning council itself may not be directly involved in the administration of a grant. If a planning council member has a financial interest in an entity, this individual may not participate in the process of selecting entities to be grant recipients.

Grievance Procedures for Planning Councils (Sec. 3402(g))
Planning councils must establish procedures for addressing grievances related to funding.

Public Deliberations of Planning Councils (Sec. 3402(h))
Planning council meetings must be open to the public, keep detailed minutes, and make publicly available records and minutes. Personal information, including personal medical information, is exempt from these public disclosure requirements.

Labor Neutrality (Sec. 3402(i))
Funding should be prioritized for grantees with a collective bargaining agreement or labor neutrality policy, as well certain policies on employee rights disclosure and voluntary union recognition.

SECTION 3403: AMOUNT OF GRANT, USE OF AMOUNTS, FUNDING AGREEMENT

Amount of Grant (Sec. 3403(a))
Grant funds shall be calculated and distributed to each local area whose application under section 3404 is approved, through formula or supplemental grants.

Formula grants: The Secretary must distribute 53 percent of the grants to local areas through formula grants. Each local area receives funding equal to 53 percent of total local area appropriations, multiplied by each local area's share of total drug overdose deaths for all eligible local areas. However, the number of non-fatal overdoses may be used to determine a local area's share of funding if that factor results in a higher distribution than would be provided using total drug overdose deaths.

- Drug overdose deaths are defined as the number of drug overdose deaths during the most recent three-year period for which data are available. Non-fatal drug overdose numbers may be calculated on the basis of data such as emergency department syndromic data, visits, other emergency medical services for drug-related causes, or Overdose Detection Mapping Application Program (ODMAP) data during the most recent three-year period for which such data are available.
- *Study of formula funding data:* The Comptroller General must conduct a study to determine whether the data used in this funding formula are the most precise way to measure local prevalence and need or if other data would be better. The Comptroller

General must make recommendations for revising the distribution factors used in this section in order to direct funds to the local areas most in need of funding.

- *Formula funding reductions:* If a local area loses eligibility for funding, the area would be eligible for 80 percent of the funding it received during the previous year in the first year of ineligibility and 50 percent of previous funding during the subsequent year.

Competitive ("supplemental") grants: The remaining 47 percent of funds appropriated for local areas must be disbursed through competitive grants to local areas that submit applications to the Secretary.

- *Application requirements:* Areas seeking competitive grants must provide a report about the use of the formula grants; demonstrate need on an objective and quantified basis for supplemental funding; demonstrate the existing commitment of resources to preventing, treating, and managing substance use disorder and supporting sustained recovery; demonstrate the ability of the area to effectively utilize supplemental financial resources; demonstrate that resources will be allocated in accordance with the local demographic incidence of substance use disorder and drug overdose mortality; demonstrate consistency of proposed services with local needs assessment and the state plan for the prevention and treatment of substance use disorder; demonstrate success in identifying individuals with substance use disorder, and demonstrate that support for substance use disorder prevention and treatment services is organized to maximize the value to the population to be served with an appropriate mix of treatment services and attention to transition in care.
- *Amount of competitive grants:* In determining the size of competitive grants, the Secretary shall consider the rate of drug overdose deaths and the increasing need for substance use disorder treatment services in the local area, including the relative rates of increase in overdoses, or recent increases not reflected in the data used to determine formula grant funding.
    - *Determining the need for a competitive grant:* When evaluating local need, the Secretary may include factors such as the unmet need for services, relative rates of increase in the number of drug overdoses or drug overdose deaths within new or emerging subpopulations, the prevalence of substance use disorders, the cost and complexity of delivering services to individuals in the local area, the impact of co-morbid factors, the prevalence of homelessness among individuals with substance use disorders, other factors that limit access to health care, the impact of a decline in formula grant funding on services available, and the increasing incidence in conditions related to substance use, including the prevalence of HIV, Hepatitis B and C, and other infections associated with injection drug use.
- Local areas receiving only competitive grant funding do not have to establish local planning councils or meet the eligibility requirements identified for local areas qualifying for formula funding.

Tribal government funds: Ten percent of funds available to provide formula grants to local areas must be provided to Indian tribes disproportionately affected by substance use, in an amount determined pursuant to a formula and eligibility criteria developed in consultation with the Indian tribes. Indian tribes may use the funds they receive for the purposes for which any of the

funding provided under this Section may be used, and for any other activities deemed appropriate by the Secretary in consultation with the tribes.

Use of Amounts (Sec. 3403(b))
Grant funds awarded to local areas may be expended only to provide prevention services, core medical services, recovery and support services, early intervention services, harm reduction services, financial assistance with health insurance, and administrative expenses.

Direct financial assistance: Local areas must use grant funds to provide direct financial assistance to eligible entities or providers for the purpose of providing prevention services, core medical services, recovery and support services, early intervention services, and harm reduction services. Direct financial assistance may be provided to public or nonprofit entities, or Medicaid providers if more than half of their patients are diagnosed with a substance use disorder and covered by Medicaid, or other private for-profit entities if such entities are the only available provider of quality substance use disorder treatment services in the area. Direct financial assistance may only be provided to an entity or provider that provides medication for addiction treatment if that entity or provider also offers mental health services and/or psychotherapy by licensed clinicians through a referral or onsite. To the extent practicable, local areas shall prioritize the distribution of funding to grantees that have a collective bargaining agreement or an explicit policy of neutrality towards organized labor and towards employees that choose to form labor unions.

- **Prevention services** are evidence-based services, programs, or multi-sector strategies to prevent substance use disorder, including education campaigns, community-based prevention programs, risk identification programs, opioid diversion, services to at-risk populations, and trauma support services. Local areas are limited to using no more than 20 percent of their total grant funding for prevention services but are allowed to apply to the Secretary for a waiver of this limit.
- **Core medical services** are evidence-based services provided to individuals with a substance use disorder or at risk for developing a substance use disorder, including through telemedicine or hub and spoke models, such as disease assessments, treatment planning, stabilization services, withdrawal management and detoxification; the provision of medication for substance use disorder; intensive inpatient or outpatient treatment; outpatient treatment; residential recovery treatment; treatment for co-occurring mental health and substance use disorders; Food and Drug Administration (FDA)-approved drugs for the treatment of substance use disorder; outpatient and ambulatory health services (including those administered by Federally qualified health centers, rural health clinics, tribal clinics and hospitals, urban Indian organizations, certified community behavioral health clinics, HIV services organizations, Native Hawaiian organizations, and comprehensive opioid services); hospice services; mental health services; opioid overdose reversal drug procurement, distribution, and training; pharmaceutical assistance and diagnostic testing related to the management of substance use disorders and co-morbid conditions; home-and-community based services; comprehensive case management; health insurance enrollment and cost-sharing assistance; and programs that hire, employ, train, and dispatch licensed health care professionals, mental health

professionals, harm reduction providers, or community health workers to respond in lieu of law enforcement in emergencies involving substance use disorder.

- **Recovery and support services** are services, subject to the approval of the Secretary, provided to individuals with substance use disorder, including residential recovery housing, mental health services, long term recovery services, 24/7 hotline crisis center support, medical transportation services, respite care for persons caring for individuals with substance use disorder, child care and family services provided while an individual is receiving inpatient treatment services or at the time of outpatient services, outreach services, peer recovery services, nutrition services, and referrals for job training and career services, housing, legal, and child and family services. Entities may not exclude individuals because they are receiving medication for addiction treatment.
- **Early intervention services** are services to provide screening and connection to substance use disorder and mental health treatment; counseling for individuals who have misused substances, who have experienced an overdose, or who are at risk of developing substance use disorder; and referrals to facilitate the access of such individuals to core medical services or recovery and support services. The entities through which services may be provided include emergency rooms, fire departments and emergency medical services, detention facilities, prisons and jails, homeless shelters, health care points of entry specified by eligible areas, federally-qualified health centers, workforce agencies and job centers, youth development centers, tribal clinics and hospitals, urban Indian organizations, and rural health clinics.
- **Harm reduction services** are services provided to individuals engaging in substance use that are scientifically accepted to reduce the risk of infectious disease transmission, overdose, or death, including syringe services programs, and other safe use services, such as utilization of a device, kit, or chemical agent that tests or analyzes a substance to determine its composition or that detects substances.
- **Financial assistance:** A local area may use grant funds to establish a program of financial assistance to assist individuals with substance use disorder in enrolling in health insurance coverage or affording health care services, including paying cost-sharing amounts.

Administrative restriction: During the first year of a grant, a local area cannot use more than 15 percent of its total grant for administration, accounting, reporting, and program oversight, including for the purposes of developing systems to improve data collection and data. In all subsequent years, no more than ten percent of grant funding can be used for administration and planning.

Incarcerated individuals: Funds received by eligible local areas may be used to provide substance use disorder treatment services to individuals who are currently incarcerated or in pre-trial detention.

Required Terms for Grants (Sec. 3403 (c))
The Secretary may not make a grant available to a local area unless:

- *Medicaid provider status:* Any services that are available pursuant to the State's Medicaid plan are provided by entities that have a participation agreement under the State's Medicaid plan and are qualified to receive payments under this plan. Any entity

that provides a Medicaid-covered service must seek payment for such service through the State Medicaid program.

  - *Waiver:* These requirements may be waived if the entity providing health care services does not impose a charge or accept third-party reimbursement for its services. A waiver cannot last longer than two years and cannot be renewed.

- *Payer of last resort:* Grant funds shall be used to make payments for any item or service only if payment cannot be made under any other State or Federal compensation or health benefits program or any insurance policy, except for programs administered by or providing services to the Indian Health Service (IHS).
- *Medication for Addiction Treatment (MAT):* All entities receiving grant funding that provide substance use disorder treatment services must offer all drugs approved by FDA for the treatment of substance use disorder.
- *Supplementation:* Funds received from a grant must be used to supplement rather than supplant other State or local funds.
- *Maintenance of Effort:* The political subdivisions within the local area receiving a grant must maintain a level of expenditures for substance use-disorder treatment services at least equal to the level of such expenditures in the preceding fiscal year and the political subdivisions will not use grant funds to meet this maintenance of effort requirement.
- *Ability to Pay:* Substance use disorder treatment services provided with grant funds must be made available without regard to ability to pay for such services or to current or past health conditions.
- *Accessibility:* Services must be provided in a setting accessible to low-income individuals with substance use disorder and to individuals in rural areas, and a program of outreach must be provided to these individuals.
- *Indian Tribes:* At least one representative from any Indian tribes located in the eligible local area must be included in the membership of a planning council.
- *Confidentiality:* The confidentiality of individuals receiving treatment must be maintained.

SECTION 3403: APPLICATION

A local area must prepare and submit an application for a grant in such form—and containing such information—as the Secretary may require, including:

1. An accounting of the use of prior grants, results achieved by these grants, and a demonstration that past funds were expended in accordance with priorities established by the planning council;
2. Establishment of goals and objectives to be achieved and how they advance the State plan for the prevention and treatment of substance use disorder;
3. A demonstration that funds will be used in compliance with section 3435 (below);
4. A demonstration that grant funds will be allocated in accordance with the local demographic incidence of substance use;
5. An explanation of how certain criteria will be established and applied to those who qualify for assistance;
6. An explanation of how an eligible local area will support, through distribution of resources and by other means, increased access to harm reduction services

7. Where practicable, an explanation of how an eligible local area shall coordinate with local public health departments in the distribution of funding; and
8. Data on outcomes achieved by prior funding received under this grant.

Requirements Regarding Imposition of Charges for Services (Sec. 3404(b))
To receive a grant, a local area must provide assurances that:

1. Individuals with income below 150 percent of poverty will not be charged for services funded by the grant;
2. For individuals with income above 150 percent of poverty, providers will impose charges according to a public schedule;
3. Individuals with incomes between 150 percent and 200 percent of poverty will pay no more than two percent of income;
4. Individuals with incomes between 200 percent and 250 percent of poverty will pay no more than four percent of income;
5. Individuals with incomes between 250 percent and 300 percent of poverty will pay no more than six percent of income;
6. Individuals with incomes between 300 percent and 400 percent of poverty will pay no more than 8.5 percent of income;
7. Individuals with incomes above 400 percent of poverty will pay not more than 8.5 percent of income; and
8. Charges will not be imposed for treatment services provided through a grant to any eligible American Indian or Alaska Native individuals.

Providers may choose to impose only a nominal charge for providing services and local areas may take into account the total medical expenses of individuals in assessing the amounts charged. The limitation on charges applies to a specific list of charges however charges are characterized, including enrollment fees, premiums, deductibles, cost-sharing, co-payments, co-insurance, and any other charges.

Indian Tribes (Sec. 3404(c))
Any requirements imposed on applications from Indian tribes must be developed by the Secretary in consultation with the tribes.

SECTION 3405: TECHNICAL ASSISTANCE

The Secretary must provide technical assistance to newly eligible local areas to help them establish planning councils and assist entities in complying with the requirements of this subtitle. The Secretary is authorized to make planning grants available to eligible areas, in amounts not to exceed $75,000, which shall be subtracted from the first year’s formula award to such areas.

SECTION 3406: FUNDING LEVEL

Funding for grants to local areas is authorized at $3.3 billion per year for ten years.

SUBTITLE B (Grants to States)

SECTION 3411: ESTABLISHMENT OF PROGRAM OF GRANTS

This section establishes a grant program, administered by the Secretary of HHS, to be awarded to States, territories, and tribal governments for the purpose of addressing substance use.

SECTION 3412: AMOUNT OF GRANT, USE OF AMOUNTS, AND FUNDING AGREEMENT

Amount of Grant to States and Territories (Sec. 3412(a))
Grant funds shall be calculated and distributed to each state whose application under section 3413 is approved, through formula or supplemental grants.

Formula Grants: The Secretary will disburse 50 percent of the amount appropriated under this Subtitle to States within 90 days after an appropriation becomes available. Each State, the District of Columbia, and the territory of Puerto Rico will receive the greater of a minimum allotment of $2 million or an amount determined through a specified formula. Other territories will receive a minimum allotment of $500,000.

- *The formula:* The State formula is the total appropriation available for formula grants multiplied by each State's share of total drug overdose deaths. The distribution factor is weighted toward States that have more deaths occurring outside local areas that are already eligible for local-area grants under Subtitle A. The Secretary must determine the overall funding level provided to a State or territory on the basis of the higher of either the number of fatal drug overdoses or the number of non-fatal drug overdoses. Drug overdose deaths and non-fatal drug overdose numbers calculated as in Subtitle A.
- *Study of formula funding data:* Same as in Subtitle A.

Competitive (supplemental) Grants: The remaining 50 percent of funds appropriated for States must be disbursed as competitive grants to States that submit an application to the Secretary.

- *Application requirements:* The same as for competitive grants under Subtitle A.
- *Amount of competitive grants & determination of need:* The Secretary shall consider the same factors as under Subtitle A.
- *Conditions for Competitive Grants:*
  - *Model standards:* Between fiscal year 2024 and fiscal year 2026, preference in the award of competitive grants shall be given to a State that has adopted the model standards for substance use disorder treatment and recovery residences developed under Section 3435. Beginning in 2026, any State that has not adopted the model standards will not be eligible to receive a grant through the competitive process.
  - *Continuum of care:* Between fiscal year 2024 and fiscal year 2026, preference in the award of competitive grants shall be given to a State that ensures the full continuum of care is covered under the state's Medicaid program in accordance with Sec. 3435. Beginning in fiscal year 2026, any State that does not cover the full continuum of care in its Medicaid program will not be eligible to receive a grant through the competitive process.

- *Utilization management for MAT:* A state that has prohibited prior authorization and step therapy requirements for at least one drug in each class approved by FDA for the treatment of substance use disorder shall receive preference in the award of competitive grants. Additional preference shall be given to States that have prohibited prior authorization for at least two or more drugs in each class approved by FDA for the treatment of substance use disorder.

Tribal government funds: Ten percent of funds available to provide formula grants to states must be provided to Indian tribes in an amount determined pursuant to a formula and eligibility criteria developed in consultation with the Indian tribes. Indian tribes may use the funds for the purposes for which any of the funding provided under this Section may be used, and for any other activities deemed appropriate by the Secretary in consultation with the tribes.

Use of Amounts (Sec. 3412(b))
States may use grant funds to provide prevention services, core medical services, recovery and support services, early intervention and engagement services, harm reduction services, and administrative expenses. Such terms are defined as in Subtitles A, except that this section limits a State to using no more than ten percent of its total grant for administration, accounting, reporting, and program oversight, including for the purposes of developing systems to improve data collection and data sharing. Funds received by states may be used to provide substance use disorder treatment services to individuals who are currently incarcerated or in pre-trial detention. Funding should be prioritized for grantees with a collective bargaining agreement or labor neutrality policy, as well certain policies on employee rights disclosure and voluntary union recognition.

SECTION 3413: APPLICATION

A State will not be eligible to receive a grant unless the State has in effect a state plan approved pursuant to Sec. 1932(b). All other requirements are the same as for the grants distributed under Subtitle A.

SECTION 3414: TECHNICAL ASSISTANCE

The Secretary must provide technical assistance in administering and coordinating activities authorized under section 3412 and in helping States apply for supplementary grants.

SECTION 3415: FUNDING LEVEL

Funding for grants to States is authorized at $4.6 billion per year for ten years.

SUBTITLE C (Grants to Clinics and Nonprofits)

SECTION 3421: ESTABLISHMENT OF GRANT PROGRAM

This section establishes a grant program administered by the Secretary to award grants to public entities, nonprofit entities, Indian entities, and other eligible Medicaid providers for the purpose of funding core medical services, recovery and support services, early intervention and engagement services, harm reduction services, and administrative expenses. Funding should be prioritized for grantees with a labor neutrality policy, as well certain policies on employee rights disclosure and voluntary union recognition

Eligibility (Sec. 3421(b))
Entities may include: Entities eligible to receive funding under this Subtitle include Federally-qualified health centers; family planning clinics; rural health clinics, Indian entities including Indian health programs, urban Indian organizations, and Native Hawaiian organizations; community-based organizations, clinics, hospitals, and other facilities that provide treatment services; other nonprofit entities providing treatment services; certified community behavioral health clinics and certified community health clinic expansion grant recipients; and other Medicaid providers if more than half of their patients are diagnosed with substance use disorder and are covered by Medicaid.

Eligible entities shall serve underserved populations, which may include minority and Indian populations; formerly incarcerated individualss; individuals with co-morbidities including HIV/AIDS and Hepatitis B or C; individuals with mental health disorderor other behavioral health disorders; low-income populations; people with disabilities; urban populations; rural populations; LGBTQ community; and pregnant individuals with substance use disorder and infants with neonatal abstinence syndrome.

Application:
The application must include:

1. An accounting of the use of prior grants and results achieved by the expenditure of those grants;
2. A comprehensive plan for the use of the grant funds;
3. A demonstration that funds will be used in compliance with section 3435 (below);
4. Information on the number of individuals to be served by the funds;
5. A demonstration that grant funds will be allocated in accordance with the local demographic incidence of substance use;
6. An explanation of how certain criteria will be established and applied to those who qualify for assistance; and
7. Data on outcomes of achieved through the use of prior funding received under this grant.

Required Terms:

- *Medicaid Provider Status:* Same definition and waiver as in Subtitles A and B.
- *Grant is the payer of last resort*, except for programs administered by or providing services to IHS.
- *MAT:* All entities receiving grant funding that provide substance use disorder treatment services must offer all drugs approved by FDA for the treatment of substance use disorder.

- *Ability to Pay:* Treatment services provided with grant funds must be made available without regard to ability to pay for such services or to current or past health conditions.
- *Accessibility:* Services must be provided in a setting accessible to low-income individuals with substance use disorder and to individuals in rural areas.
- *Confidentiality:* The confidentiality of individuals receiving treatment must be maintained.

Indian Entities (Sec. 3421(c))
Ten percent of the grant funds shall be used to provide grants to Indian entities in amounts determined pursuant to criteria developed by the Secretary in consultation with Indian tribes and after conferring with urban Indian organizations. Native entities may use grant amounts for the purposes for which any grant under Section 3422 may be used as well as any other activities deemed appropriate by the Secretary in consultation with the Indian tribes.

SECTION 3422: USE OF AMOUNTS

An eligible entity may use these grants to provide prevention services, core medical services, recovery and support services, early intervention and engagement services, harm reduction services, and administrative expenses. Such terms are defined as in Subtitles A, except that this section limits an eligible entity to using no more than ten percent of its total grant for administration, accounting, reporting, and program oversight, including for the purposes of developing systems to improve data collection and data sharing. Nothing in this section should be construed to diminish or alter the rights, privileges, remedies or obligations of any provider or Federal, State, or local government to provide emergency medical services.

SECTION 3423: TECHNICAL ASSISTANCE

The Secretary may provide technical assistance to public or nonprofit entities, Indian entities, and other eligible Medicaid providers regarding the process of submitting grants and may provide technical assistance with respect to the planning, development, and operation of any program or service.

SECTION 3424: PLANNING AND DEVELOPMENT GRANTS

The Secretary may provide planning grants to eligible entities for purposes of assisting such entities and providers in expanding their capacity to provide evidence-based substance-use related health and support services in low-income communities and underserved populations. Such grants made shall not exceed $150,000.

SECTION 3425: FUNDING LEVEL

Funding for grants to clinics and non-profits is authorized at $1 billion per year for ten years.

SUBTITLE D (Innovation, Training, and Health Systems Strengthening)

SECTION 3431: SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE

The Secretary shall award grants to entities to administer special projects of national significance to support the development of innovative and original models for the delivery of substance use disorder treatment and harm reduction services based on newly emerging needs of individuals receiving assistance under this title.

Eligible entities: Entities that are eligible for grants under subtitles A, B, and C are eligible for grants under this section.

Replication and Coordination of Projects (Sec. 3431(c))
The Secretary shall make information regarding successful models or programs developed under this section available to grantees in order to facilitate coordination, replication, and integration. The Secretary may provide for peer-based technical assistance for grantees funded under this section.

Grants to Tribal Governments (Sec. 3431(d))
The Secretary must use ten percent of the funding made available for special projects of national significance to provide grants to Indian tribes for the purposes of supporting the development of innovative and original models for the delivery of substance use treatment services, including the development of culturally-informed care models.

Funding Level (Sec. 3431(e))

Funding for special projects of national significant is authorized at $500 million per year for ten years.

SECTION 3432: EDUCATION AND TRAINING CENTERS

The Secretary will make grants and enter into contracts to assist public and nonprofit entities, public or nonprofit schools, and academic medical centers in meeting the costs of projects to:

- Train health professionals, including, but not limited to, physician addiction specialists, psychologists, counselors, case managers, social workers, peer recovery coaches, harm reduction workers, public health workers, and community health workers, and paraprofessionals, such as peer support specialists and recovery coaches, in the diagnosis, treatment, and prevention of substance use disorders and drug use-related health issues, including measures for the prevention and treatment of co-occurring infectious diseases and other conditions and care for women, pregnant women, and children;
- Train the faculty of schools of medicine and other health professions to teach students to screen for and provide for the needs of individuals with substance use disorder or at risk of substance use disorder and to develop and disseminate curricula and resource materials related to the screening, prevention, and treatment of substance use disorder and drug use-related health issues, including information about prescribing best practices, overdose reversal, alternative pain therapies, and medication for addiction treatment; and
- Develop and disseminate curricula and resource materials.

Preference in Making Grants (Sec. 3432(a))
The Secretary shall give preference to qualified projects that will train or result in the training of:

- Health professionals who will provide services for underserved groups;
- Minority health professionals and minority-allied health professionals;
- Professionals who will provide treatment in rural or other areas underserved by current treatment structures;
- Professionals who will provide treatment for infectious diseases and mental health conditions co-occurring with substance use disorder; and
- Professionals who provide services to pregnant women, children, and adolescents.

Native Education and Training Centers (Sec. 3432(c))
The Secretary must use ten percent of the amounts made available for education and training centers to provide grants to tribal colleges and universities, IHS grant-funded institutions, and Native partner institutions, including institutions of higher education with medical training programs that partner with one or more Indian tribes, tribal organizations, native Hawaiian organizations, or tribal colleges and universities to train Native health professionals who will provide substance use disorder treatment services in Native communities.

Funding Level (Sec. 3432(d))

Funding for grants to education and training centers is authorized at $500 million per year for ten years.

SECTION 3433: SUBSTANCE USE DISORDER TREATMENT PROVIDER CAPACITY UNDER THE MEDICAID PROGRAM

The Secretary shall fund projects in any State or territory to increase the capacity of substance use providers under the Medicaid program, as authorized under the SUPPORT Act. Funding should be prioritized for grantees with a labor neutrality policy, as well certain policies on employee rights disclosure and voluntary union recognition

Eligible Project Purposes include ongoing assessments of the behavioral health treatment needs of a State; technical assistance for Medicaid providers; improved reimbursement for and expansion of Medicaid providers that can prescribe MAT; and improved reimbursement for and expansion of Medicaid providers that treat individuals with neonatal abstinence syndrome pregnant and postpartum women, infants, adolescents, young adults, and American Indian and Alaska Native individuals.

Amount of Grant to Indian Entities (Sec. 3433(b))
The Secretary, acting through IHS, must use ten percent of the amount appropriated to award grants to Indian entities.

Funding Level (Sec. 3433(c))

Funding to expand provider capacity is authorized at $50 million per year for ten years.

SECTION 3434: PROGRAMS TO SUPPORT EMPLOYEES

Grant Program for Workers (Sec. 3434(a))
The Secretary, acting through the Director of the National Institute for Occupational Safety and Health (NIOSH), will award grants to non-profit entities for programs to assist workers at risk for, experiencing, or in recovery from substance use disorder to maintain or gain employment. Grants may be awarded up to three years in duration.

Use of amounts: Funding for grants awarded under this section may be used to provide prevention services, early intervention services, recovery and support services, and harm reduction services, or to hire staff to assist employees, or to provide vocational and other forms of job training to individuals receiving treatment services.

Individuals described: Individuals eligible to receive assistance under this section include those who have been employed in the 12-month period preceding the date of the determination and are at high risk of developing substance use disorder, or those who are experiencing a substance use disorder or who are in recovery.

Application: The application must include:

1. An accounting of the use of prior grants and results achieved by these grants;
2. A description of the population to be served;
3. Goals and objectives to be achieved;
4. A demonstration that the applicant can provide services to eligible individuals; and
5. Data on outcomes of results achieved with prior funding received under this grant.

Annual reporting: Entities must submit annual reports to the Secretary, including reports on activities funded by the grant and the number of individuals who maintained or gained employment.

Funding level: Funding for grants for workers is authorized at $40 million per year for ten years.

Research on the Impact of Substance Use Disorder in the Workplace and on Direct Service Providers (Sec. 3434(b))
The Secretary, in consultation with the Director of NIOSH, will conduct research, experiments, and demonstrations on workers' risks, the prevalence of substance use disorders, efforts employers can take to help employees, and the risks of occupational exposure to illicit substances. The Secretary will also conduct research, experiments and demonstrations on occupational health and safety, and the recruitment and retention of behavioral health providers.

Funding level: Funding for research on workers is authorized at $10 million per year for ten years.

SECTION 3435: IMPROVING AND EXPANDING CARE

Level of Care Standards for Treatment Services (Sec. 3435(a))
Within one year, the Secretary, in consultation with the American Society of Addiction Medicine (ASAM),State and tribal officials selected by the Secretary , and other stakeholders as the Secretary determines necessary, after seeking public input, will promulgate model standards for the regulation of substance use disorder treatment services.

The model standards shall:
- Identify the type of providers covered;
- Require the designation of a single State agency to serve as the primary regulator;
- Require that all treatment services to be licensed by States according to levels of care set forth by ASAM;
- Require a process for onsite inspection at least every three years; and
- Require patients leaving a residential treatment program to receive a written transition plan.

The Secretary will conduct an annual assessment beginning in 2022 to determine if States have adopted the model standards.

Standards for Other Specified Matters Related to Substance Use Disorder Treatment Services and Recovery Residences (Sec. 3435(b))
Within two years, the Secretary, in consultation with stakeholders, will promulgate model standards for the regulation of:
- Professional credentials for each type of substance use disorder treatment professional;
- Standards for data reporting and the compilation of statewide reports;
- Establishment and maintenance of State toll-free telephone numbers to receive complaints about treatment providers;
- Establishment and maintenance of a publicly accessible internet site listing all certified treatment services in the State; and
- Recovery residences.
  - Standards for recovery residences must include: designation of a single State agency to certify residences; requirement for on-sight inspections at least every three years; fire, safety, and health standards; standards for equipping such residences with naloxone and training residence owners, operators, and employees in the administration of naloxone; a written policy prohibiting exclusion of individuals receiving MAT; establishment and maintenance of a toll-free phone number to receive complaints about recovery residents; and establishment and maintenance of a publicly accessible internet site listing all recovery residences in the State.

The Secretary will conduct an annual assessment beginning in 2025 to determine if States have adopted the model standards for recovery residences.

Ensuring Access to Medication for Substance Use Disorder (Sec. 3435(c))
An applicant may not receive a grant unless the applicant agrees to require all entities offering treatment under the grant to offer all drugs approved by FDA for the treatment of substance use disorder for which the applicant offers treatment. Waivers may be granted if the entity agrees to

offer at least two drugs approved to treat the substance use disorder for which the applicant offers treatment so long as the applicant agrees to require all entities offering treatment under the grant to provide counseling to patients on MAT, and maintain an affiliation agreement with another provider that can prescribe or dispense all other forms of MAT.

Government Accountability Office (GAO) Study: Within a year, GAO shall conduct a study describing any relationship between substance use rates, pain management practices of IHS, and patient request denials through the purchased or referred care program of IHS.

Ensuring a Full Continuum of Services (Sec. 3435(d))
Within six months of enactment, the Centers for Medicare & Medicaid Services will issue a State Medicaid Director letter and tribal leader letter explaining how to ensure access to a continuum of services for adults with substance use disorder receiving medical assistance under the Medicaid program.

Medicaid and CHIP Payment and Access Commission (MACPAC) Analysis: Within a year, MACPAC will prepare a report analyzing states' coverage of substance use disorder services for Medicaid beneficiaries.

Assessment: Beginning in 2022, the Secretary will conduct an annual assessment to determine if States have ensured coverage under their Medicaid programs of the full continuum of care.

SECTION 3436: NALOXONE DISTRIBUTION PROGRAM

The Secretary must provide for the purchase and delivery of opioid overdose reversal products (currently, Naloxone) approved by FDA on behalf of each State and Indian tribe that receives funding under subtitle B. This section authorizes $1 billion annually for ten years in advance of appropriations Acts and represents the obligation of the Federal Government to provide for the purchase and delivery to States and Indian tribes of opioid overdose reversal products.

In the event that sufficient overdose reversal drug products are not available, this section directs the Secretary to give preference to States with at least one local area eligible to receive a formula grant for local areas under Section 3401.

Negotiation of Contracts with Manufacturers (Sec. 3436(b))
The Secretary must negotiate with manufacturers of opioid overdose reversal products. The Secretary is authorized to decline to enter into contracts or modify or extend contracts as necessary. The price for these drug products shall be a discounted price negotiated by the Secretary.

The Secretary must provide for the purchase and delivery of these products on behalf of States and tribal organizations and allow each State and Indian tribe to obtain additional quantities of opioid overdose reversal products at the same discounted price.

The Secretary must enter into initial negotiations no later than 180 days after the enactment of this title.

The Secretary may enter into a contract with a drug manufacturer only if the manufacturer agrees to submit such reports as the Secretary deems necessary to ensure compliance with the contract and if the manufacturer agrees not to impose additional delivery costs.

The Secretary may enter into contracts with multiple manufacturers, provided each manufacturer meets the terms and conditions of the contract, and allows States to choose which contract will be applicable to their purchase of additional quantities of overdose reversal products.

Beginning no later than one year after the Secretary enters into the first contract under this Section, the Secretary shall use a list established by an advisory committee established by the Secretary and located within the Centers for Disease Control (CDC), which considers the cost-effectiveness of each overdose reversal product as the basis for the purchase, delivery, and administration of these products.

States must distribute opioid overdose reversal products received under this section to first responders, public entities with the authority to administer local public health services, nonprofit entities, and the general public.

In order to be eligible to receive opioid overdose reversal drugs under this section, each State shall establish a program for distributing these products to first responders, nonprofit entities, the general public, and local health departments, demonstrate a distribution rate of a minimum of 90 percent of the opioid overdose reversal products received under this program, and certify to the Secretary that the State has in place measures that enhance access to opioid overdose reversal products.

IHS, in consultation with Indian tribes, must determine any requirements that shall apply to Indian tribes receiving opioid overdose reversal products through the program established by this section.

SECTION 3437: ADDITIONAL FUNDING FOR THE NATIONAL INSTITUTES OF HEALTH

Ten years of appropriations, totaling $10 billion, are authorized to the National Institutes of Health for the purposes of conducting research on addiction and pain and to develop opioid overdose reversal drug products, and non-opioid drug products and non-pharmacological treatments for pain and substance use disorder.

SECTION 3438: ADDITIONAL FUNDING FOR THE CENTERS FOR DISEASE CONTROL AND PREVENTION

Ten years of appropriations, totaling $5 billion, are authorized to the CDC for the purposes of improving data on drug overdose deaths and non-fatal drug overdoses, surveillance related to

addiction and substance use disorder, and the prevention of transmission of infectious diseases related to substance use.

The CDC must use portions of the funding appropriated under this section to: (1) ensure all States participate in the Enhanced State Opioid Overdose Surveillance program and to provide technical assistance to medical examiners and coroners to facilitate improved data collection; (2) improve data; and (3) improve Tribal data. A portion of the funding will also be used to collect data on adverse childhood experiences and to screen for worker health risks. This section requires that not less than 1.5 percent of the funding made available to the CDC be provided to Indian Tribes and tribal epidemiology centers.

SECTION 4: AMENDMENTS TO CONTROLLED SUBSTANCES ACT

Certifications Relating to Diversion Controls (Sec. 4(b))
Not later than 180 days after the enactment of this section and each year thereafter, each covered officer (a president, CEO, chief medical officer, or chief council) of a covered entity (distributor, dispenser, or manufacturer) must submit to the Attorney General, for each schedule II controlled substance, a signed certification that the covered entity maintains effective controls against diversion of the controlled substance, information contained in any record, inventory, or report required to be kept or submitted to the Attorney General is accurate, and that the company is in compliance with all applicable requirements under Federal law to report suspicious orders for controlled substances.

Certifications Relating to Misbranding (Sec. 4(c))
Not more than 180 days after enactment and each year thereafter, each covered officer of a covered entity must submit a signed certification to the Secretary of HHS that the controlled substance is not misbranded, as defined in section 502 of the Food, Drug, and Cosmetic Act. If this certification is not submitted or contains false statements, the Secretary must notify the Attorney General.

Practitioners of opioid treatment programs dispensing Medication for Addiction Treatment are exempt from the diversion control and misbranding certification requirements.

Failure to submit certifications or submission of false certifications: It is unlawful to fail to submit these certifications or to submit a certification that contains a materially false statement or representation relating to the controls against diversion or the misbranding of the controlled substance. Covered officers are subject to civil penalties of a fine of not more than $25,000 if they fail to submit a certification or submit a false certification. If covered officers willfully submit a false certification, they can be subject to criminal penalties specified under section 403(d) of the Controlled Substances Act of not more than four years imprisonment.

Establishment of a "Comprehensive Addiction Resources Emergency Fund": 100 percent of any civil penalty or criminal fine paid to the federal government under this section is directed to the fund and the fund can be used to supplement the grants established by this Act.

SECTION 5: USE OF FUNDS

Amounts appropriated or provided under this Act shall be used only for public health purposes described in the Act and shall not be used to fund the incarceration, institutionalization, or involuntary use of treatment of individuals to address the illicit use of substances; or procure equipment or support activities inconsistent with the public health purposes described in the bill.

SECTION 6: FEDERAL DRUG DEMAND REDUCTION ACTIVITES

Requires the Office of National Drug Control Policy to evaluate the effectiveness of all federally funded reduction activities and to publish annually a complete list of all drug control grant programs.