

[~116H7527]



(Original Signature of Member)

117TH CONGRESS
1ST SESSION

H. R. _____

To rescue domestic medical manufacturing activity by providing incentives
in economically distressed areas of the United States and its possessions.

IN THE HOUSE OF REPRESENTATIVES

Miss GONZÁLEZ-COLÓN introduced the following bill; which was referred to
the Committee on _____

A BILL

To rescue domestic medical manufacturing activity by pro-
viding incentives in economically distressed areas of the
United States and its possessions.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medical Manufac-
5 turing, Economic Development, and Sustainability Act of
6 2021” or the “MMEDS Act of 2021”.

1 **SEC. 2. ECONOMICALLY DISTRESSED ZONES.**

2 (a) IN GENERAL.—Chapter 1 of the Internal Rev-
3 enue Code of 1986 is amended by adding at the end the
4 following new subchapter:

5 **“Subchapter AA—Medical Manufacturing in**
6 **Economically Distressed Zones**

“SUBCHAPTER AA—MEDICAL MANUFACTURING IN ECONOMICALLY DISTRESSED
ZONES

“Sec. 1400AA–1. Medical manufacturing in economically distressed zone credit.

“Sec. 1400AA–2. Credit for economically distressed zone products and services
acquired by domestic medical manufacturers.

“Sec. 1400AA–3. Special rules to secure the national supply chain and for the
production of population health products.

“Sec. 1400AA–4. Designation of economically distressed zones.

7 **“SEC. 1400AA–1. MEDICAL MANUFACTURING IN ECONOMI-**
8 **CALLY DISTRESSED ZONE CREDIT.**

9 “(a) ALLOWANCE OF CREDIT.—There shall be al-
10 lowed as a credit against the tax imposed by subtitle A
11 for the taxable year an amount equal 40 percent of the
12 sum of—

13 “(1) the aggregate amount of the taxpayer’s
14 medical manufacturing economically distressed zone
15 wages for such taxable year,

16 “(2) the allocable employee fringe benefit ex-
17 penses of the taxpayer for such taxable year, and

18 “(3) the depreciation and amortization allow-
19 ances of the taxpayer for the taxable year with re-
20 spect to qualified medical manufacturing facility
21 property.

1 “(b) DENIAL OF DOUBLE BENEFIT.—Any wages or
2 other expenses taken into account in determining the cred-
3 it under this section may not be taken into account in de-
4 termining the credit under sections 41, and any other pro-
5 vision determined by the Secretary to be substantially
6 similar.

7 “(c) DEFINITIONS AND SPECIAL RULES.—For pur-
8 poses of this section—

9 “(1) ECONOMICALLY DISTRESSED ZONE
10 WAGES.—

11 “(A) IN GENERAL.—The term ‘economi-
12 cally distressed zone wages’ means amounts
13 paid or incurred for wages of an employee by
14 the taxpayer for the taxable year which are—

15 “(i) in connection with the active con-
16 duct of a trade or business of the taxpayer,
17 and

18 “(ii) paid or incurred for an employee
19 the principal place of employment of whom
20 is in a qualified medical manufacturing fa-
21 cility of such taxpayer.

22 “(B) LIMITATION ON AMOUNT OF WAGES
23 TAKEN INTO ACCOUNT.—

24 “(i) IN GENERAL.—The amount of
25 wages which may be taken into account

1 under subparagraph (A) with respect to
2 any employee for any taxable year shall
3 not exceed the contribution and benefit
4 base determined under section 230 of the
5 Social Security Act for the calendar year
6 in which such taxable year begins.

7 “(ii) TREATMENT OF PART-TIME EM-
8 PLOYEES, ETC.—If—

9 “(I) any employee is not em-
10 ployed by the taxpayer on a substan-
11 tially full-time basis at all times dur-
12 ing the taxable year, or

13 “(II) the principal place of em-
14 ployment of any employee is not with-
15 in an economically distressed zone at
16 all times during the taxable year,

17 the limitation applicable under clause (i)
18 with respect to such employee shall be the
19 appropriate portion (as determined by the
20 Secretary) of the limitation which would
21 otherwise be in effect under clause (i).

22 “(C) TREATMENT OF CERTAIN EMPLOY-
23 EES.—The term ‘economically distressed zone
24 wages’ shall not include any wages paid to em-
25 ployees who are assigned by the employer to

1 perform services for another person, unless the
2 principal trade or business of the employer is to
3 make employees available for temporary periods
4 to other persons in return for compensation.

5 “(D) WAGES.—For purposes of this para-
6 graph, the term ‘wages’ shall not include any
7 amounts which are allocable employee fringe
8 benefit expenses.

9 “(2) ALLOCABLE EMPLOYEE FRINGE BENEFIT
10 EXPENSES.—

11 “(A) IN GENERAL.—The term ‘allocable
12 employee fringe benefit expenses’ means the ag-
13 gregate amount allowable as a deduction under
14 this chapter to the taxpayer for the taxable year
15 for the following amounts which are allocable to
16 employment in a qualified medical manufac-
17 turing facility and which are not included as
18 economically distressed zone wages pursuant to
19 this subsection:

20 “(i) Employer contributions under a
21 stock bonus, pension, profit-sharing, or an-
22 nuity plan.

23 “(ii) Employer-provided coverage
24 under any accident or health plan for em-
25 ployees.

1 “(iii) The cost of life or disability in-
2 surance provided to employees.

3 “(B) ALLOCATION.—For purposes of sub-
4 paragraph (A), an amount shall be treated as
5 allocable to a qualified medical manufacturing
6 facility only if such amount is with respect to
7 employment of an individual for services pro-
8 vided, and the principal place of employment of
9 whom is, in such facility.

10 “(3) QUALIFIED MEDICAL MANUFACTURING FA-
11 CILITY.—The term ‘qualified medical manufacturing
12 facility’ means any facility that—

13 “(A) researches and develops or produces
14 medical products or essential components of
15 medical products, and

16 “(B) is located within an economically dis-
17 tressed zone.

18 “(4) QUALIFIED MEDICAL MANUFACTURING FA-
19 CILITY PROPERTY.—The term ‘qualified medical
20 manufacturing facility property’ means any property
21 used in (or consisting of) a qualified medical manu-
22 facturing facility if such property is directly con-
23 nected to the research, development, or production
24 of a medical product.

1 “(5) MEDICAL PRODUCT; ESSENTIAL COMPO-
2 NENT.—

3 “(A) MEDICAL PRODUCT.—The term ‘med-
4 ical product’ means—

5 “(i) a drug that—

6 “(I) is a prescription drug sub-
7 ject to regulation under section 505 of
8 the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 355) or section
10 351 of the Public Health Service Act
11 (42 U.S.C. 262),

12 “(II) is subject to regulation
13 under section 802 of the Federal
14 Food, Drug, and Cosmetic Act (21
15 U.S.C. 382), or

16 “(III) is described in section
17 201(jj) of such Act (21 U.S.C.
18 321(jj)), or

19 “(ii) a device, as defined in section
20 201(h) of such Act (21 U.S.C. 321(h)).

21 “(B) ESSENTIAL COMPONENT.—The term
22 ‘essential component’ means, with respect to a
23 medical product—

24 “(i) an active pharmaceutical ingre-
25 dient, or

1 “(ii) a protein, antibody, enzyme, hor-
2 mone, or other organic material that is an
3 active ingredient in a biological product.

4 “(6) AGGREGATION RULES.—

5 “(A) IN GENERAL.—For purposes of this
6 section, members of an affiliated group shall be
7 treated as a single taxpayer.

8 “(B) AFFILIATED GROUP.—The term ‘af-
9 filiated group’ means an affiliated group (as de-
10 fined in section 1504(a), determined without re-
11 gard to section 1504(b)(3)) one or more mem-
12 bers of which are engaged in the active conduct
13 of a trade or business within an economically
14 distressed zone.

15 **“SEC. 1400AA-2. CREDIT FOR ECONOMICALLY DISTRESSED**
16 **ZONE PRODUCTS AND SERVICES ACQUIRED**
17 **BY DOMESTIC MEDICAL MANUFACTURERS.**

18 “(a) ALLOWANCE OF CREDIT.—In the case of an eli-
19 gible medical manufacturer, there shall be allowed as a
20 credit against the tax imposed by subtitle A for the taxable
21 year an amount equal to the applicable percentage of the
22 aggregate amounts paid or incurred by the taxpayer dur-
23 ing such taxable year for qualified economically distressed
24 zone products or services.

1 “(b) APPLICABLE PERCENTAGE.—For purposes of
2 this section, the term applicable percentage means—

3 “(1) 30 percent in the case of amounts paid or
4 incurred to persons not described in paragraph (2)
5 or (3),

6 “(2) 40 percent in the case of amounts paid or
7 incurred to an unrelated minority business, and

8 “(3) 5 percent in the case of amounts paid or
9 incurred to a related person.

10 “(c) ELIGIBLE MEDICAL MANUFACTURER.—For
11 purposes of this section, the term ‘eligible medical manu-
12 facturer’ means any person in the trade or business of pro-
13 ducing medical products in the United States.

14 “(d) QUALIFIED PRODUCT OR SERVICE.—For pur-
15 poses of this section, the term ‘qualified product or service’
16 means—

17 “(1) any product which is produced in an eco-
18 nomically distressed zone and which is integrated
19 into a medical product produced by the taxpayer,
20 and

21 “(2) any service which is provided in an eco-
22 nomically distressed zone and which is necessary to
23 the production of a medical product by the taxpayer
24 (including packaging).

1 “(e) MINORITY BUSINESS.—For purposes of this sec-
2 tion—

3 “(1) IN GENERAL.—The term ‘minority busi-
4 ness’ means—

5 “(A) a sole proprietorship carried on by a
6 qualified individual, or

7 “(B) a corporation or partnership—

8 “(i) at least 50 percent of the owner-
9 ship interests in which are held by one or
10 more qualified individuals, and

11 “(ii) of which a qualified individual is
12 the president or chief executive officer (or
13 a substantially equivalent position).

14 “(2) QUALIFIED INDIVIDUAL.—The term ‘quali-
15 fied individual’ means any individual who—

16 “(A) is of Asian-Indian, Asian-Pacific,
17 Black, Hispanic, or Native American origin or
18 descent, and

19 “(B) is a United States citizen or legal
20 resident of the United States or any of its terri-
21 tories or possessions.

22 “(f) RELATED PERSONS.—For purposes of this sec-
23 tion, persons shall be treated as related to each other if
24 such persons would be treated as a single employer under
25 the regulations prescribed under section 52(b).

1 “(g) OTHER TERMS.—Terms used in this section
2 which are also used in section 1400AA–1 shall have the
3 same meaning as when used in such section.

4 **“SEC. 1400AA–3. SPECIAL RULES TO SECURE THE NATIONAL**
5 **SUPPLY CHAIN AND FOR THE PRODUCTION**
6 **OF POPULATION HEALTH PRODUCTS.**

7 “(a) IN GENERAL.—In the case of a qualified repatri-
8 ated medical manufacturing facility or a qualified popu-
9 lation health product manufacturing facility—

10 “(1) section 1400AA–1(a) shall be applied by
11 substituting ‘60 percent’ for ‘40 percent’, and

12 “(2) section 1400AA–2(a) shall be applied—

13 “(A) by substituting ‘50 percent’ for ‘30
14 percent’, and

15 “(B) by substituting ‘60 percent’ for ‘40
16 percent’.

17 “(b) ELECTION TO EXPENSE IN LIEU OF TAX CRED-
18 IT FOR DEPRECIATION.—In the case of a taxpayer which
19 elects (at such time and in such manner as the Secretary
20 may provide) the application of this subsection with re-
21 spect to any qualified repatriated medical manufacturing
22 facility or qualified population health product manufac-
23 turing facility—

1 “(1) section 1400AA–1(a)(3) shall not apply
2 with respect to any qualified medical manufacturing
3 facility property with respect to such facility, and

4 “(2) for purposes of section 168(k)—

5 “(A) such property shall be treated as
6 qualified property, and

7 “(B) the applicable percentage with respect
8 to such property shall be 100 percent.

9 “(c) QUALIFIED REPATRIATED MEDICAL MANUFAC-
10 TURING FACILITY.—For purposes of this section, the term
11 ‘qualified repatriated medical manufacturing facility’
12 means any qualified medical manufacturing facility (as de-
13 fined in section 1400AA–1) the production of which was
14 moved to an economically distressed zone from a foreign
15 country that the United States Trade Representative has
16 determined could pose a risk to the national supply chain
17 because of political or social factors.

18 “(d) QUALIFIED POPULATION HEALTH PRODUCT
19 MANUFACTURING FACILITY.—For purposes of this sec-
20 tion, the term ‘qualified population health product manu-
21 facturing facility’ means any qualified medical manufac-
22 turing facility (as defined in section 1400AA–1) that pro-
23 duces a population health product (as defined in section
24 319L(a)(11) of the Public Health Service Act) which the
25 Secretary of Health and Human Services has identified

1 for support through a strategic initiative under section
2 319L(c)(4)(F)(ii) of the Public Health Service Act.

3 **“SEC. 1400AA-4. DESIGNATION OF ECONOMICALLY DIS-**
4 **TRESSED ZONES.**

5 “(a) IN GENERAL.—For purposes of this subchapter,
6 the term ‘economically distressed zone’ means any popu-
7 lation census tract within the United States which—

8 “(1) has a poverty rate of not less than 35 per-
9 cent for each of the 5 most recent calendar years for
10 which information is available, or

11 “(2) satisfies each of the following require-
12 ments:

13 “(A) has pervasive poverty, unemployment,
14 low labor force participation, and general dis-
15 tress measured as a prolonged period of eco-
16 nomic decline measured by real gross national
17 product,

18 “(B) has a poverty rate of not less than 30
19 percent for each of the 5 most recent calendar
20 years for which information is available, and

21 “(C) has been designated as such by the
22 Secretary and the Secretary of Commerce pur-
23 suant to an application under subsection (b).

24 “(b) APPLICATION FOR DESIGNATION.—

1 “(1) IN GENERAL.—An application for designa-
2 tion as an economically distressed zone may be filed
3 by a State or local government in which the popu-
4 lation census tract to which the application applies
5 is located.

6 “(2) REQUIREMENTS.—Such application shall
7 include a strategic plan for accomplishing the pur-
8 poses of this subchapter, which—

9 “(A) describes the coordinated economic,
10 human, community, and physical development
11 plan and related activities proposed for the
12 nominated area,

13 “(B) describes the process by which the af-
14 fected community is a full partner in the proc-
15 ess of developing and implementing the plan
16 and the extent to which local institutions and
17 organizations have contributed to the planning
18 process,

19 “(C) identifies the amount of State, local,
20 and private resources that will be available in
21 the nominated area and the private/public part-
22 nerships to be used, which may include partici-
23 pation by, and cooperation with, universities,
24 medical centers, and other private and public
25 entities,

1 “(D) identifies the funding requested
2 under any Federal program in support of the
3 proposed economic, human, community, and
4 physical development and related activities,

5 “(E) identifies baselines, methods, and
6 benchmarks for measuring the success of car-
7 rying out the strategic plan, including the ex-
8 tent to which poor persons and families will be
9 empowered to become economically self-suffi-
10 cient, and

11 “(F) does not include any action to assist
12 any establishment in relocating from one area
13 outside the nominated area to the nominated
14 area, except that assistance for the expansion of
15 an existing business entity through the estab-
16 lishment of a new branch, affiliate, or sub-
17 sidiary is permitted if—

18 “(i) the establishment of the new
19 branch, affiliate, or subsidiary will not re-
20 sult in a decrease in employment in the
21 area of original location or in any other
22 area where the existing business entity
23 conducts business operations,

24 “(ii) there is no reason to believe that
25 the new branch, affiliate, or subsidiary is

1 being established with the intention of clos-
2 ing down the operations of the existing
3 business entity in the area of its original
4 location or in any other area where the ex-
5 isting business entity conducts business op-
6 eration, and

7 “(iii) includes such other information
8 as may be required by the Secretary and
9 the Secretary of Commerce.

10 “(c) PERIOD FOR WHICH DESIGNATIONS ARE IN EF-
11 fect.—Designation as an economically distressed zone
12 may be made at any time during the 10-year period begin-
13 ning on the date of the enactment of this section, and shall
14 remain in effect with respect to such zone during the 15-
15 year period beginning on the date of such designation.
16 Economically distressed zones described in subsection
17 (a)(1) shall take effect on the date of the enactment of
18 this Act and shall remain in effect during the 15-year pe-
19 riod beginning on such date.

20 “(d) TERRITORIES AND POSSESSIONS.—The term
21 ‘United States’ includes the 50 States, the District of Co-
22 lumbia, and the territories and possessions of the United
23 States.

24 “(e) REGULATIONS.—The Secretary shall issue such
25 regulations or other guidance as may be necessary or ap-

1 appropriate to carry out the purposes of this section, includ-
2 ing—

3 “(1) not later than 30 days after the date of
4 the enactment of this section, a list of the population
5 census tracts described in subsection (a)(1), and

6 “(2) not later than 60 days after the date of
7 the enactment of this section, regulations or other
8 guidance regarding the designation of population
9 census tracts described in subsection (a)(2).”.

10 (b) EFFECTIVE DATE.—The amendments made by
11 this section shall apply to taxable years beginning after
12 December 31, 2020.

13 **SEC. 3. AUTHORITY TO SUPPORT DEVELOPMENT OF POPU-**
14 **LATION HEALTH PRODUCTS.**

15 (a) DEFINITIONS.—

16 (1) QUALIFIED COUNTERMEASURE.—Subpara-
17 graph (A) of section 319F–1(a)(2) of the Public
18 Health Service Act (42 U.S.C. 247d–6a(a)(2)) is
19 amended to read as follows:

20 “(A) QUALIFIED COUNTERMEASURE.—The
21 term ‘qualified countermeasure’ means a drug
22 (as that term is defined by section 201(g)(1) of
23 the Federal Food, Drug, and Cosmetic Act (21
24 U.S.C. 321(g)(1))), biological product (as that
25 term is defined by section 351(i) of this Act (42

1 U.S.C. 262(i))), or device (as that term is de-
2 fined by section 201(h) of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 321(h))),
4 that the Secretary determines to be a priority
5 consistent with sections 302(2) and 304(a) of
6 the Homeland Security Act of 2002—

7 “(i) to diagnose, mitigate, prevent, or
8 treat harm from any biological agent (in-
9 cluding organisms that cause an infectious
10 disease), toxin, chemical, radiological, or
11 nuclear agent that may cause a public
12 health emergency affecting national secu-
13 rity; or

14 “(ii) to diagnose, mitigate, prevent, or
15 treat harm from an underlying non-com-
16 municable disease which, combined with
17 pandemic influenza or an emerging infec-
18 tious disease, may result in adverse health
19 consequences or serious threat to one or
20 more vulnerable American populations (as
21 defined in section 319L(a)) in an epidemic
22 or pandemic.”.

23 (2) OTHER DEFINITIONS.—Subsection (a) of
24 section 319L of the Public Health Service Act (42

1 U.S.C. 247d–7e) is amended by adding at the end
2 the following new paragraphs:

3 “(11) POPULATION HEALTH PRODUCT.—The
4 term ‘population health product’ means a widely
5 available drug to diagnose, mitigate, prevent, or
6 treat harm from an underlying non-communicable
7 disease which, combined with pandemic influenza or
8 an emerging infectious disease, may result in ad-
9 verse health consequences or a serious threat to one
10 or more vulnerable American populations in an epi-
11 demic or pandemic.

12 “(12) VULNERABLE AMERICAN POPU-
13 LATIONS.—The term ‘vulnerable American popu-
14 lations’ means children, pregnant women, older
15 adults, minority populations, and other at-risk indi-
16 viduals with relevant characteristics that warrant
17 consideration during the process of researching and
18 developing such countermeasures and products.”.

19 (b) STRATEGIC INITIATIVES.—Clause (ii) of section
20 319L(c)(4)(F) of the Public Health Service Act (42
21 U.S.C. 247d–7e(c)(4)(F)) is amended to read as follows:

22 “(ii) threats that consistently exist or
23 continually circulate and have a significant
24 potential to become a pandemic, such as
25 pandemic influenza and emerging infec-

1 tious diseases in combination with under-
2 lying non-communicable diseases, which
3 may include the advanced research and de-
4 velopment, manufacturing, and appropriate
5 stockpiling of qualified pandemic or epi-
6 demic products, and products, technologies,
7 or processes to support the advanced re-
8 search and development of such counter-
9 measures (including multiuse platform
10 technologies for diagnostics, vaccines, and
11 therapeutics; virus seeds; clinical trial lots;
12 novel virus strains; and antigen and adju-
13 vant material); and”.

14 (c) AT-RISK INDIVIDUALS.—Paragraph (6) of section
15 319L(c) of the Public Health Service Act (42 U.S.C.
16 247d–7e(c)) is amended to read as follows:

17 “(6) AT-RISK INDIVIDUALS.—In carrying out
18 the functions under this section, the Secretary may
19 give a priority to advanced research and develop-
20 ment of—

21 “(A) qualified countermeasures and quali-
22 fied pandemic or epidemic products likely to be
23 safe and effective with respect to vulnerable
24 American populations; and

1 “(B) population health products likely to
2 protect vulnerable American populations with
3 underlying non-communicable diseases from dis-
4 proportionate harm in epidemics and
5 pandemics.”.

6 (d) OTHER AUTHORITIES.—Section 319L(c) of the
7 Public Health Service Act (42 U.S.C. 247d–7e(c)) is
8 amended by adding at the end the following:

9 “(8) TIMELY DELIVERY OF POPULATION
10 HEALTH PRODUCTS TO AT-RISK INDIVIDUALS.—The
11 Secretary shall collaborate with the Administrator of
12 the Centers for Medicare & Medicaid Services, the
13 Secretary of Defense, the Secretary of Veterans Af-
14 fairs, the Commissioner of Food and Drugs, and the
15 heads of other Federal agencies involved with ap-
16 proval and distribution of health products to assure
17 that such Federal agencies distribute approved pop-
18 ulation health products as promptly and effectively
19 as possible, and as continuously as possible, to pro-
20 tect vulnerable American populations from harm in
21 epidemics and pandemics.

22 “(9) REPORT ON NEED FOR INCENTIVIZING DE-
23 VELOPMENT OF POPULATION HEALTH PRODUCTS.—
24 Not later than 90 days after the date of enactment
25 of the Medical Manufacturing, Economic Develop-

1 ment, and Sustainability Act of 2021, the Secretary
2 shall examine and report to the Congress on—

3 “(A) the extent to which the health of
4 aging Americans, African Americans, His-
5 panics, Native Americans, veterans, or other
6 vulnerable American populations has been dis-
7 proportionately harmed by the COVID–19 pan-
8 demic and prior epidemics and pandemics;

9 “(B) the population health products cur-
10 rently available and whether there is a need for
11 additional innovation and development to
12 produce population health products to reduce
13 the exposure of vulnerable American popu-
14 lations to risk of disproportionate harm in
15 epidemics and pandemics; and

16 “(C) whether the Secretary recommends
17 providing the same incentives for the develop-
18 ment and marketing of population health prod-
19 ucts as is given with respect to covered infec-
20 tious disease products under the Federal Food,
21 Drug, and Cosmetic Act, including under sec-
22 tion 505E of such Act.”.