

**AMENDMENT TO RULES COMMITTEE PRINT 117-**  
**31**  
**OFFERED BY MISS GONZÁLEZ-COLÓN OF PUERTO**  
**RICO**

Page 434, after line 9, insert the following:

1 **SEC. 10409. 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—

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

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

6           “(3) the depreciation and amortization allow-  
7           ances of the taxpayer for the taxable year with re-  
8           spect to qualified medical manufacturing facility  
9           property.

10          “(b) DENIAL OF DOUBLE BENEFIT.—Any wages or  
11          other expenses taken into account in determining the cred-  
12          it under this section may not be taken into account in de-  
13          termining the credit under sections 41, and any other pro-  
14          vision determined by the Secretary to be substantially  
15          similar.

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

18                 “(1) ECONOMICALLY DISTRESSED ZONE  
19                 WAGES.—

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

1 “(i) in connection with the active con-  
2 duct of a trade or business of the taxpayer,  
3 and

4 “(ii) paid or incurred for an employee  
5 the principal place of employment of whom  
6 is in a qualified medical manufacturing fa-  
7 cility of such taxpayer.

8 “(B) LIMITATION ON AMOUNT OF WAGES  
9 TAKEN INTO ACCOUNT.—

10 “(i) IN GENERAL.—The amount of  
11 wages which may be taken into account  
12 under subparagraph (A) with respect to  
13 any employee for any taxable year shall  
14 not exceed the contribution and benefit  
15 base determined under section 230 of the  
16 Social Security Act for the calendar year  
17 in which such taxable year begins.

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

20 “(I) any employee is not em-  
21 ployed by the taxpayer on a substan-  
22 tially full-time basis at all times dur-  
23 ing the taxable year, or

24 “(II) the principal place of em-  
25 ployment of any employee is not with-

1           in an economically distressed zone at  
2           all times during the taxable year,  
3           the limitation applicable under clause (i)  
4           with respect to such employee shall be the  
5           appropriate portion (as determined by the  
6           Secretary) of the limitation which would  
7           otherwise be in effect under clause (i).

8           “(C) TREATMENT OF CERTAIN EMPLOY-  
9           EES.—The term ‘economically distressed zone  
10          wages’ shall not include any wages paid to em-  
11         ployees who are assigned by the employer to  
12         perform services for another person, unless the  
13         principal trade or business of the employer is to  
14         make employees available for temporary periods  
15         to other persons in return for compensation.

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

20          “(2) ALLOCABLE EMPLOYEE FRINGE BENEFIT  
21         EXPENSES.—

22                 “(A) IN GENERAL.—The term ‘allocable  
23         employee fringe benefit expenses’ means the ag-  
24         gregate amount allowable as a deduction under  
25         this chapter to the taxpayer for the taxable year

1 for the following amounts which are allocable to  
2 employment in a qualified medical manufac-  
3 turing facility and which are not included as  
4 economically distressed zone wages pursuant to  
5 this subsection:

6 “(i) Employer contributions under a  
7 stock bonus, pension, profit-sharing, or an-  
8 nuity plan.

9 “(ii) Employer-provided coverage  
10 under any accident or health plan for em-  
11 ployees.

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

14 “(B) ALLOCATION.—For purposes of sub-  
15 paragraph (A), an amount shall be treated as  
16 allocable to a qualified medical manufacturing  
17 facility only if such amount is with respect to  
18 employment of an individual for services pro-  
19 vided, and the principal place of employment of  
20 whom is, in such facility.

21 “(3) QUALIFIED MEDICAL MANUFACTURING FA-  
22 CILITY.—The term ‘qualified medical manufacturing  
23 facility’ means any facility that—

1           “(A) researches and develops or produces  
2           medical products or essential components of  
3           medical products, and

4           “(B) is located within an economically dis-  
5           tressed zone.

6           “(4) QUALIFIED MEDICAL MANUFACTURING FA-  
7           CILITY PROPERTY.—The term ‘qualified medical  
8           manufacturing facility property’ means any property  
9           used in (or consisting of) a qualified medical manu-  
10          facturing facility if such property is directly con-  
11          nected to the research, development, or production  
12          of a medical product.

13          “(5) MEDICAL PRODUCT; ESSENTIAL COMPO-  
14          NENT.—

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

17                  “(i) a drug that—

18                          “(I) is a prescription drug sub-  
19                          ject to regulation under section 505 of  
20                          the Federal Food, Drug, and Cos-  
21                          metic Act (21 U.S.C. 355) or section  
22                          351 of the Public Health Service Act  
23                          (42 U.S.C. 262),

24                          “(II) is subject to regulation  
25                          under section 802 of the Federal

1 Food, Drug, and Cosmetic Act (21  
2 U.S.C. 382), or

3 “(III) is described in section  
4 201(jj) of such Act (21 U.S.C.  
5 321(jj)), or

6 “(ii) a device, as defined in section  
7 201(h) of such Act (21 U.S.C. 321(h)).

8 “(B) ESSENTIAL COMPONENT.—The term  
9 ‘essential component’ means, with respect to a  
10 medical product—

11 “(i) an active pharmaceutical ingre-  
12 dient, or

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

16 “(6) AGGREGATION RULES.—

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

20 “(B) AFFILIATED GROUP.—The term ‘af-  
21 filiated group’ means an affiliated group (as de-  
22 fined in section 1504(a), determined without re-  
23 gard to section 1504(b)(3)) one or more mem-  
24 bers of which are engaged in the active conduct

1           of a trade or business within an economically  
2           distressed zone.

3   **“SEC. 1400AA-2. CREDIT FOR ECONOMICALLY DISTRESSED**  
4                   **ZONE PRODUCTS AND SERVICES ACQUIRED**  
5                   **BY DOMESTIC MEDICAL MANUFACTURERS.**

6           “(a) ALLOWANCE OF CREDIT.—In the case of an eli-  
7   gible medical manufacturer, there shall be allowed as a  
8   credit against the tax imposed by subtitle A for the taxable  
9   year an amount equal to the applicable percentage of the  
10 aggregate amounts paid or incurred by the taxpayer dur-  
11 ing such taxable year for qualified economically distressed  
12 zone products or services.

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

15               “(1) 30 percent in the case of amounts paid or  
16   incurred to persons not described in paragraph (2)  
17   or (3),

18               “(2) 40 percent in the case of amounts paid or  
19   incurred to an unrelated minority business, and

20               “(3) 5 percent in the case of amounts paid or  
21   incurred to a related person.

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



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

4           “(1) any product which is produced in an eco-  
5 nomically distressed zone and which is integrated  
6 into a medical product produced by the taxpayer,  
7 and

8           “(2) any service which is provided in an eco-  
9 nomically distressed zone and which is necessary to  
10 the production of a medical product by the taxpayer  
11 (including packaging).

12           “(e) MINORITY BUSINESS.—For purposes of this sec-  
13 tion—

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

16           “(A) a sole proprietorship carried on by a  
17 qualified individual, or

18           “(B) a corporation or partnership—

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

22           “(ii) of which a qualified individual is  
23 the president or chief executive officer (or  
24 a substantially equivalent position).

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

3                   “(A) is of Asian-Indian, Asian-Pacific,  
4                   Black, Hispanic, or Native American origin or  
5                   descent, and

6                   “(B) is a United States citizen or legal  
7                   resident of the United States or any of its terri-  
8                   tories or possessions.

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

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

16          **“SEC. 1400AA-3. SPECIAL RULES TO SECURE THE NATIONAL**  
17   **SUPPLY CHAIN AND FOR THE PRODUCTION**  
18   **OF POPULATION HEALTH PRODUCTS.**

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

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

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

1                   “(A) by substituting ‘50 percent’ for ‘30  
2                   percent’, and

3                   “(B) by substituting ‘60 percent’ for ‘40  
4                   percent’.

5           “(b) ELECTION TO EXPENSE IN LIEU OF TAX CRED-  
6 IT FOR DEPRECIATION.—In the case of a taxpayer which  
7 elects (at such time and in such manner as the Secretary  
8 may provide) the application of this subsection with re-  
9 spect to any qualified repatriated medical manufacturing  
10 facility or qualified population health product manufac-  
11 turing facility—

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

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

16                           “(A) such property shall be treated as  
17                           qualified property, and

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

20           “(c) QUALIFIED REPATRIATED MEDICAL MANUFAC-  
21 TURING FACILITY.—For purposes of this section, the term  
22 ‘qualified repatriated medical manufacturing facility’  
23 means any qualified medical manufacturing facility (as de-  
24 fined in section 1400AA–1) the production of which was  
25 moved to an economically distressed zone from a foreign

1 country that the United States Trade Representative has  
2 determined could pose a risk to the national supply chain  
3 because of political or social factors.

4 “(d) QUALIFIED POPULATION HEALTH PRODUCT  
5 MANUFACTURING FACILITY.—For purposes of this sec-  
6 tion, the term ‘qualified population health product manu-  
7 facturing facility’ means any qualified medical manufac-  
8 turing facility (as defined in section 1400AA–1) that pro-  
9 duces a population health product (as defined in section  
10 319L(a)(11) of the Public Health Service Act) which the  
11 Secretary of Health and Human Services has identified  
12 for support through a strategic initiative under section  
13 319L(c)(4)(F)(ii) of the Public Health Service Act.

14 **“SEC. 1400AA–4. DESIGNATION OF ECONOMICALLY DIS-**  
15 **TRESSED ZONES.**

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

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

22 “(2) satisfies each of the following require-  
23 ments:

24 “(A) has pervasive poverty, unemployment,  
25 low labor force participation, and general dis-

1           tress measured as a prolonged period of eco-  
2           nomic decline measured by real gross national  
3           product,

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

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

10       “(b) APPLICATION FOR DESIGNATION.—

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

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

19                   “(A) describes the coordinated economic,  
20           human, community, and physical development  
21           plan and related activities proposed for the  
22           nominated area,

23                   “(B) describes the process by which the af-  
24           fected community is a full partner in the proc-  
25           ess of developing and implementing the plan

1 and the extent to which local institutions and  
2 organizations have contributed to the planning  
3 process,

4 “(C) identifies the amount of State, local,  
5 and private resources that will be available in  
6 the nominated area and the private/public part-  
7 nerships to be used, which may include partici-  
8 pation by, and cooperation with, universities,  
9 medical centers, and other private and public  
10 entities,

11 “(D) identifies the funding requested  
12 under any Federal program in support of the  
13 proposed economic, human, community, and  
14 physical development and related activities,

15 “(E) identifies baselines, methods, and  
16 benchmarks for measuring the success of car-  
17 rying out the strategic plan, including the ex-  
18 tent to which poor persons and families will be  
19 empowered to become economically self-suffi-  
20 cient, and

21 “(F) does not include any action to assist  
22 any establishment in relocating from one area  
23 outside the nominated area to the nominated  
24 area, except that assistance for the expansion of  
25 an existing business entity through the estab-

1            lishment of a new branch, affiliate, or sub-  
2            sidiary is permitted if—

3                    “(i) the establishment of the new  
4                    branch, affiliate, or subsidiary will not re-  
5                    sult in a decrease in employment in the  
6                    area of original location or in any other  
7                    area where the existing business entity  
8                    conducts business operations,

9                    “(ii) there is no reason to believe that  
10                   the new branch, affiliate, or subsidiary is  
11                   being established with the intention of clos-  
12                   ing down the operations of the existing  
13                   business entity in the area of its original  
14                   location or in any other area where the ex-  
15                   isting business entity conducts business op-  
16                   eration, and

17                   “(iii) includes such other information  
18                   as may be required by the Secretary and  
19                   the Secretary of Commerce.

20            “(c) PERIOD FOR WHICH DESIGNATIONS ARE IN EF-  
21            FECT.—Designation as an economically distressed zone  
22            may be made at any time during the 10-year period begin-  
23            ning on the date of the enactment of this section, and shall  
24            remain in effect with respect to such zone during the 15-  
25            year period beginning on the date of such designation.

1 Economically distressed zones described in subsection  
2 (a)(1) shall take effect on the date of the enactment of  
3 this Act and shall remain in effect during the 15-year pe-  
4 riod beginning on such date.

5 “(d) TERRITORIES AND POSSESSIONS.—The term  
6 ‘United States’ includes the 50 States, the District of Co-  
7 lumbia, and the territories and possessions of the United  
8 States.

9 “(e) REGULATIONS.—The Secretary shall issue such  
10 regulations or other guidance as may be necessary or ap-  
11 propriate to carry out the purposes of this section, includ-  
12 ing—

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

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

20 (b) EFFECTIVE DATE.—The amendments made by  
21 this section shall apply to taxable years beginning after  
22 December 31, 2021.

23 **SEC. 10410. AUTHORITY TO SUPPORT DEVELOPMENT OF**  
24 **POPULATION HEALTH PRODUCTS.**

25 (a) DEFINITIONS.—



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

5           “(A) QUALIFIED COUNTERMEASURE.—The  
6 term ‘qualified countermeasure’ means a drug  
7 (as that term is defined by section 201(g)(1) of  
8 the Federal Food, Drug, and Cosmetic Act (21  
9 U.S.C. 321(g)(1))), biological product (as that  
10 term is defined by section 351(i) of this Act (42  
11 U.S.C. 262(i))), or device (as that term is de-  
12 fined by section 201(h) of the Federal Food,  
13 Drug, and Cosmetic Act (21 U.S.C. 321(h))),  
14 that the Secretary determines to be a priority  
15 consistent with sections 302(2) and 304(a) of  
16 the Homeland Security Act of 2002—

17           “(i) to diagnose, mitigate, prevent, or  
18 treat harm from any biological agent (in-  
19 cluding organisms that cause an infectious  
20 disease), toxin, chemical, radiological, or  
21 nuclear agent that may cause a public  
22 health emergency affecting national secu-  
23 rity; or

24           “(ii) to diagnose, mitigate, prevent, or  
25 treat harm from an underlying non-com-

1           municable disease which, combined with  
2           pandemic influenza or an emerging infec-  
3           tious disease, may result in adverse health  
4           consequences or serious threat to one or  
5           more vulnerable American populations (as  
6           defined in section 319L(a)) in an epidemic  
7           or pandemic.”.

8           (2) OTHER DEFINITIONS.—Subsection (a) of  
9           section 319L of the Public Health Service Act (42  
10          U.S.C. 247d–7e) is amended by adding at the end  
11          the following new paragraphs:

12           “(11) POPULATION HEALTH PRODUCT.—The  
13          term ‘population health product’ means a widely  
14          available drug to diagnose, mitigate, prevent, or  
15          treat harm from an underlying non-communicable  
16          disease which, combined with pandemic influenza or  
17          an emerging infectious disease, may result in ad-  
18          verse health consequences or a serious threat to one  
19          or more vulnerable American populations in an epi-  
20          demic or pandemic.

21           “(12) VULNERABLE AMERICAN POPU-  
22          LATIONS.—The term ‘vulnerable American popu-  
23          lations’ means children, pregnant women, older  
24          adults, minority populations, and other at-risk indi-  
25          viduals with relevant characteristics that warrant

1 consideration during the process of researching and  
2 developing such countermeasures and products.”.

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

6 “(ii) threats that consistently exist or  
7 continually circulate and have a significant  
8 potential to become a pandemic, such as  
9 pandemic influenza and emerging infec-  
10 tious diseases in combination with under-  
11 lying non-communicable diseases, which  
12 may include the advanced research and de-  
13 velopment, manufacturing, and appropriate  
14 stockpiling of qualified pandemic or epi-  
15 demic products, and products, technologies,  
16 or processes to support the advanced re-  
17 search and development of such counter-  
18 measures (including multiuse platform  
19 technologies for diagnostics, vaccines, and  
20 therapeutics; virus seeds; clinical trial lots;  
21 novel virus strains; and antigen and adju-  
22 vant material); and”.

23 (c) AT-RISK INDIVIDUALS.—Paragraph (6) of section  
24 319L(c) of the Public Health Service Act (42 U.S.C.  
25 247d–7e(c)) is amended to read as follows:

1           “(6) AT-RISK INDIVIDUALS.—In carrying out  
2           the functions under this section, the Secretary may  
3           give a priority to advanced research and develop-  
4           ment of—

5                   “(A) qualified countermeasures and quali-  
6                   fied pandemic or epidemic products likely to be  
7                   safe and effective with respect to vulnerable  
8                   American populations; and

9                   “(B) population health products likely to  
10                  protect vulnerable American populations with  
11                  underlying non-communicable diseases from dis-  
12                  proportionate harm in epidemics and  
13                  pandemics.”.

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

17                   “(8) TIMELY DELIVERY OF POPULATION  
18                   HEALTH PRODUCTS TO AT-RISK INDIVIDUALS.—The  
19                   Secretary shall collaborate with the Administrator of  
20                   the Centers for Medicare & Medicaid Services, the  
21                   Secretary of Defense, the Secretary of Veterans Af-  
22                   fairs, the Commissioner of Food and Drugs, and the  
23                   heads of other Federal agencies involved with ap-  
24                   proval and distribution of health products to assure  
25                   that such Federal agencies distribute approved pop-

1       ulation health products as promptly and effectively  
2       as possible, and as continuously as possible, to pro-  
3       tect vulnerable American populations from harm in  
4       epidemics and pandemics.

5               “(9) REPORT ON NEED FOR INCENTIVIZING DE-  
6       VELOPMENT OF POPULATION HEALTH PRODUCTS.—  
7       Not later than 90 days after the date of enactment  
8       of the Medical Manufacturing, Economic Develop-  
9       ment, and Sustainability Act of 2021, the Secretary  
10      shall examine and report to the Congress on—

11              “(A) the extent to which the health of  
12              aging Americans, African Americans, His-  
13              panics, Native Americans, veterans, or other  
14              vulnerable American populations has been dis-  
15              proportionately harmed by the COVID–19 pan-  
16              demic and prior epidemics and pandemics;

17              “(B) the population health products cur-  
18              rently available and whether there is a need for  
19              additional innovation and development to  
20              produce population health products to reduce  
21              the exposure of vulnerable American popu-  
22              lations to risk of disproportionate harm in  
23              epidemics and pandemics; and

24              “(C) whether the Secretary recommends  
25              providing the same incentives for the develop-

1           ment and marketing of population health prod-  
2           ucts as is given with respect to covered infec-  
3           tious disease products under the Federal Food,  
4           Drug, and Cosmetic Act, including under sec-  
5           tion 505E of such Act.”.

