

116TH CONGRESS
2D SESSION

S. 3847

To amend the Public Health Service Act to establish an Emergency Office of Manufacturing for Public Health, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 1, 2020

Ms. WARREN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to establish an Emergency Office of Manufacturing for Public Health, and for other purposes.

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 “COVID–19 Emergency
5 Manufacturing Act of 2020”.

6 **SEC. 2. PUBLIC MANUFACTURING OF PHARMACEUTICALS.**

7 Part A of title III of the Public Health Service Act
8 (42 U.S.C. 241 et seq.) is amended by adding at the end
9 the following:

1 **“SEC. 310B. MANUFACTURING OF DRUGS, BIOLOGICAL**
2 **PRODUCTS, DEVICES, AND PERSONAL PRO-**
3 **TECTIVE EQUIPMENT.**

4 “(a) EMERGENCY OFFICE OF MANUFACTURING FOR
5 PUBLIC HEALTH.—

6 “(1) ESTABLISHMENT.—There is established
7 within the Department of Health and Human Serv-
8 ices an office to be known as the Emergency Office
9 of Manufacturing for Public Health (referred to in
10 this section as the ‘Office’).

11 “(2) PURPOSE.—The purposes of the Office
12 are—

13 “(A) to ensure an adequate supply of, and
14 increase access to, prescription drugs, biological
15 products, devices, and other supplies, including
16 personal protective equipment, necessary to, as
17 appropriate, diagnose, mitigate, prevent, or
18 treat COVID–19 and to mitigate the harm the
19 COVID–19 pandemic might otherwise cause for
20 the strategic national stockpile under section
21 319F–2, Federal, State, local, and Native
22 health programs, and the commercial market;

23 “(B) to address shortages in the strategic
24 national stockpile and commercial market of
25 prescription drugs, biological products, devices,

1 and personal protective equipment used to treat
2 conditions other than COVID–19; and

3 “(C) to provide prescription drugs, biologi-
4 cal products, devices, and personal protective
5 equipment necessary to diagnose, mitigate, pre-
6 vent, and treat COVID–19 and to mitigate the
7 harm the COVID–19 pandemic might otherwise
8 cause, to Federal, State, local, and Native
9 health programs, at no cost, and to consumers
10 in the commercial market and other inter-
11 national entities at cost.

12 “(3) PERSONNEL.—

13 “(A) DIRECTOR.—

14 “(i) IN GENERAL.—The Office shall
15 be headed by a Director, who shall be ap-
16 pointed by the President, not later than 15
17 days after the date of enactment of the
18 COVID–19 Emergency Manufacturing Act
19 of 2020, by and with the advice and con-
20 sent of the Senate.

21 “(ii) ACTING DIRECTOR.—The Assist-
22 ant Secretary for Preparedness and Re-
23 sponse, if in compliance with subparagraph
24 (C), may serve as Director of the Office in
25 an acting capacity until the later of Senate

1 confirmation of a Director or 3 months
2 after date of enactment of the COVID-19
3 Emergency Manufacturing Act of 2020.

4 “(iii) COMPENSATION.—The Director
5 shall be compensated at the rate prescribed
6 for level III of the Executive Schedule
7 under section 5314 of title 5, United
8 States Code.

9 “(B) EMPLOYEES.—The Director of the
10 Office, in consultation with the Secretary, may
11 fix the number of, and appoint and direct, all
12 employees of the Office.

13 “(C) BANNED INDIVIDUALS.—

14 “(i) DRUG COMPANY LOBBYISTS.—No
15 former registered drug manufacturer lob-
16 byist—

17 “(I) may be appointed to the po-
18 sition of Director of the Office; or

19 “(II) may be employed by the Of-
20 fice during the 6-year period begin-
21 ning on the date on which the reg-
22 istered lobbyist terminates its reg-
23 istration in accordance with section
24 4(d) of the Lobbying Disclosure Act

1 of 1995 or the agent terminates its
2 status, as applicable.

3 “(ii) SENIOR EXECUTIVES OF LAW-
4 BREAKING COMPANIES.—No former senior
5 executive of a covered entity—

6 “(I) may be appointed to the po-
7 sition of Director of the Office; or

8 “(II) may be employed by the Of-
9 fice during the 6-year period begin-
10 ning on the later of—

11 “(aa) the date of the settle-
12 ment; and

13 “(bb) the date on which the
14 enforcement action has con-
15 cluded.

16 “(iii) COVERED ENTITY.—For pur-
17 poses of clause (ii), the term ‘covered enti-
18 ty’ means any entity that is—

19 “(I) a drug manufacturer; and

20 “(II)(aa) operating under Fed-
21 eral settlement, including a Federal
22 consent decree; or

23 “(bb) the subject of an enforce-
24 ment action in a court of the United
25 States or by an agency.

1 “(4) DUTIES.—

2 “(A) IN GENERAL.—The Office shall—

3 “(i) prepare and submit applications
4 for approval to the Food and Drug Admin-
5 istration, or enter into contracts for such
6 submission, for the manufacture of appli-
7 cable COVID–19 products and other appli-
8 cable drugs, biological products, and de-
9 vices when authorized under this section;

10 “(ii) obtain rights to manufacture ap-
11 plicable COVID–19 products and applica-
12 ble drugs, biological products, and devices
13 as authorized under this section;

14 “(iii) manufacture, or enter into con-
15 tracts with entities to manufacture, appli-
16 cable COVID–19 products and other appli-
17 cable drugs, biological products, and de-
18 vices as authorized under this section;

19 “(iv) determine a fair price for each
20 applicable drug, biological product, and de-
21 vice, in accordance with subparagraph
22 (B)(ii);

23 “(v) sell manufactured applicable
24 drugs, biological products, and devices at a
25 fair price, as authorized under this section;

1 “(vi) provide, at no cost, applicable
 2 COVID–19 products to Federal, State,
 3 local, and Native health programs, and
 4 other domestic health care providers and
 5 suppliers, as determined by the Secretary;

6 “(vii) sell, at-cost, applicable COVID–
 7 19 products to other commercial entities
 8 and international entities, in accordance
 9 with subparagraph (B)(i); and

10 “(viii) manufacture, or enter into con-
 11 tracts with entities to manufacture, active
 12 pharmaceutical ingredients for use by the
 13 Office or for sale to other entities.

14 “(B) PRICING DETERMINATIONS.—

15 “(i) AT-COST PRICE.—In determining
 16 an at-cost price for an applicable COVID–
 17 19 product under subparagraph (A)(vii)
 18 the Office shall consider—

19 “(I) the cost to the Federal Gov-
 20 ernment of manufacturing the appli-
 21 cable COVID–19 product;

22 “(II) the administrative costs of
 23 operating the Office; and

1 “(III) the cost to acquire or man-
2 ufacture applicable COVID-19 prod-
3 uct under this section.

4 “(ii) FAIR PRICE.—In determining a
5 fair price for an applicable drug, biological
6 product, or device under subparagraph
7 (A)(iv) the Office shall consider—

8 “(I) the impact of price on pa-
9 tient access to the applicable drug, bi-
10 ological product, or device;

11 “(II) the cost of the applicable
12 drug, biological product, or device to
13 Federal or State health care pro-
14 grams;

15 “(III) the cost to the Federal
16 Government of manufacturing the ap-
17 plicable drug, biological product, or
18 device;

19 “(IV) the administrative costs of
20 operating the Office;

21 “(V) the cost to acquire or manu-
22 facture the applicable drug, biological
23 product, or device under this section;
24 and

1 “(VI) the impact of price on
2 market competition for the applicable
3 drug, biological product, or device.

4 “(iii) TRANSPARENCY.—All prices
5 charged for applicable COVID–19 products
6 and applicable drugs, biological products,
7 or devices shall be made publicly available
8 by the Office.

9 “(C) OBTAINING RIGHTS TO MANUFAC-
10 TURE AND MARKET.—

11 “(i) IN GENERAL.—When necessary to
12 fulfill the Office’s duties under this section,
13 the Office shall acquire the rights to manu-
14 facture and market applicable COVID–19
15 products and applicable drugs, biological
16 products, and devices as authorized under
17 this section.

18 “(ii) LICENSING AUTHORITY.—

19 “(I) IN GENERAL.—Notwith-
20 standing any other provision of law,
21 the Secretary may issue licenses, as
22 useful for fulfilling the duties under
23 this Act, allowing the Office to prac-
24 tice or have practiced (which may in-
25 clude licensure of retroactive practice)

1 any invention in the United States or
2 territories of the United States, in-
3 cluding making, using, offering to sell
4 or selling, importing, or exporting
5 such invention, to reference or rely
6 upon clinical trial data submitted to a
7 regulatory authority or the grant of
8 marketing approval, and to access and
9 use otherwise confidential informa-
10 tion, including know-how, related to
11 the manufacture of an applicable
12 COVID-19 product or applicable
13 drug, biological product, or device.

14 “(II) NON-VOLUNTARY LICENS-
15 ING.—For any license that involves a
16 non-voluntary authorization to use
17 patented inventions, regulatory test
18 data, data, know-how or other intel-
19 lectual property rights, the license
20 shall provide for reasonable remunera-
21 tion to rights holders such as a rea-
22 sonable royalty on the sales of prod-
23 uct, a 1-time payment, or some com-
24 bination, provided that the combined
25 royalty payments to all rights holders

1 shall not exceed the percentage of
2 sales that is the average percent of all
3 royalty payments reported to the In-
4 ternal Revenue Service by companies
5 in the pharmaceutical and medicines
6 sector, North American Industry Clas-
7 sification System code 325410, pro-
8 vided that when products are distrib-
9 uted for free, the royalty shall be
10 based upon the cost of goods. When
11 there are multiple rights holders, the
12 allocation of the total royalty pay-
13 ments shall be determined by—

14 “(aa) agreement among the
15 rights holders;

16 “(bb) allocation by arbitra-
17 tion among the rights holders; or

18 “(cc) if neither item (aa)
19 nor (bb) applies, by the Office.

20 “(iii) TRANSPARENCY.—Subject to
21 clause (iv), the Secretary shall post any
22 contract agreement under subparagraph
23 (A) or license issued under clause (ii) on
24 the public internet website of the Depart-
25 ment of Health and Human Services, on

the date on which such agreement or license takes effect.

“(iv) PROTECTED INFORMATION.—In carrying out this section, the Secretary shall enforce applicable law concerning the protection of confidential commercial information and trade secrets.

“(D) ACTIVE PHARMACEUTICAL INGREDIENTS.—

“(i) IN GENERAL.—The Office shall manufacture, or enter into contracts with entities to manufacture, an active pharmaceutical ingredient applicable to a drug or biological product that is either an applicable COVID–19 product or an applicable drug or biological product if—

“(I) the Office determines that such ingredient is not readily available from existing suppliers or the existing supply of such ingredient to the domestic market is vulnerable to disruption;

“(II) the manufacture of such ingredient would improve the ability of other entities to enter the market for

1 the manufacture of applicable
2 COVID–19 products or applicable
3 drugs, biological products, or devices,
4 or otherwise expand the manufacture
5 of applicable COVID–19 products or
6 applicable drugs, biological products,
7 or devices; or

8 “(III) the manufacture of such
9 ingredient is necessary for the Office
10 to carry out its duties under this sec-
11 tion.

12 “(ii) PRICE DETERMINATIONS.—In
13 determining the price at which to sell an
14 active pharmaceutical ingredient manufac-
15 tured in accordance with clause (i), the Of-
16 fice shall consider the cost to manufacture
17 the ingredient, the administrative costs of
18 the Office with respect to the ingredient,
19 and the impact of such price on market
20 competition for the ingredient.

21 “(E) PRIORITY.—In awarding contracts
22 under this paragraph, the Office shall prioritize
23 entities manufacturing applicable COVID–19
24 products and applicable drugs, biological prod-

1 ucts, and devices using components originating
2 and manufactured in the United States.

3 “(F) CONTRACT REQUIREMENTS.—All con-
4 tracts issued under this paragraph shall include
5 a requirement that the contract recipients rea-
6 sonably price products produced under the con-
7 tract.

8 “(b) MANUFACTURING OF PRODUCTS.—

9 “(1) IN GENERAL.—As soon as practicable
10 after the date of enactment of this section, but no
11 later than 1 month after such date of enactment, the
12 Office shall begin—

13 “(A) manufacturing, or entering into con-
14 tracts with entities for the manufacture of ap-
15 plicable COVID–19 products and applicable
16 drugs, biological products, and devices,
17 prioritizing drugs, biological products, devices
18 or personal protective equipment the manufac-
19 ture of which would provide the greatest public
20 health impact; and

21 “(B) constructing, or entering into con-
22 tracts to construct, manufacturing facilities, in-
23 cluding the construction of advanced manufac-
24 turing technology, RNA vaccines, DNA vac-
25 cines, recombinant protein vaccines, and other

1 therapeutics, viral vector-based vaccines, live at-
2 tenuated vaccines, inactivated vaccines, or other
3 therapeutics, after clinical data relating to such
4 products have demonstrated strong positive in-
5 dications of safety and efficacy, to ensure im-
6 mediate production at-scale upon Federal ap-
7 proval.

8 “(2) SUBMISSION OF APPLICATIONS.—For each
9 applicable COVID–19 product, and for each applica-
10 ble drug, biological product, or device that the Office
11 determines should be manufactured, as provided for
12 under this section, the Secretary shall—

13 “(A) submit an application under section
14 505(b), 505(j), or 515 of the Federal Food,
15 Drug, and Cosmetic Act or section 351(a) or
16 351(k) of this Act or submit a notification
17 under section 510(k) of the Federal Food,
18 Drug, and Cosmetic Act (or enter into a con-
19 tract with another entity to submit such an ap-
20 plication or notification);

21 “(B) request an emergency use authoriza-
22 tion of the product under section 564A of the
23 Federal Food, Drug, and Cosmetic Act (or
24 enter into a contract with another entity to sub-
25 mit an application for such use); or

1 “(C) obtain from the holder of an applica-
2 tion approved under subsection (c) or (j) of sec-
3 tion 505 or section 515 of the Federal Food,
4 Drug, and Cosmetic Act or subsection (a) or
5 (k) of section 351 of the Public Health Service
6 Act, or cleared under section 510(k) of the Fed-
7 eral Food, Drug, and Cosmetic Act, rights to
8 manufacture such applicable drug.

9 “(3) MANUFACTURING TIMELINES.—

10 “(A) PERSONAL PROTECTIVE EQUIP-
11 MENT.—Not later than 1 month after the date
12 of enactment of this section, the Secretary shall
13 begin the public manufacturing of personal pro-
14 tective equipment, including surgical masks,
15 surgical gowns, face shields, and N95 masks,
16 meeting the definition of applicable COVID–19
17 product and in accordance with this section.

18 “(B) COVID–19 DIAGNOSTIC TEST MATE-
19 RIALS.—Not later than 1 month after the date
20 of enactment of this section, the Secretary shall
21 begin the public manufacturing of materials
22 necessary for the development of COVID–19 di-
23 agnostic tests, including chemical reagents, test
24 swabs, and materials necessary to develop sero-
25 logical COVID–19 tests, meeting the definition

1 of applicable COVID–19 product and in accord-
2 ance with this section.

3 “(C) COVID–19 TREATMENT DRUGS.—As
4 soon as practicable after the date of enactment
5 of this section, the Secretary shall begin the
6 public manufacturing of drugs and biological
7 products in shortage, and any devices used to
8 administer such drugs and biological products,
9 that are used for treatment of severe COVID–
10 19 cases, including albuterol, drugs used to
11 intubate patients, antibiotics, and antivirals,
12 meeting the definition of applicable COVID–19
13 product and in accordance with this section.

14 “(4) PRIORITY MANUFACTURING.—The Office
15 shall prioritize the manufacturing of applicable
16 COVID–19 products and applicable drugs, biological
17 products, and devices that would have the greatest
18 impact on—

19 “(A) diagnosing, mitigating, preventing,
20 treating, or curing COVID–19;

21 “(B) limiting the harm the COVID–19
22 pandemic might otherwise cause to public
23 health and the economy;

24 “(C) addressing shortages of drugs, bio-
25 logical, products, and devices;

1 “(D) reducing the cost of combating
2 COVID–19 to Federal, State, local, and Native
3 health programs; and

4 “(E) alleviating demographic disparities in
5 COVID–19 outcomes or access to diagnosis,
6 mitigation, prevention, and treatment.

7 “(c) PROVISION OF PRODUCTS.—

8 “(1) PROVISION OF APPLICABLE COVID–19
9 PRODUCTS.—The Secretary shall provide applicable
10 COVID–19 products at no cost to Federal, State,
11 local, and Native health programs, and other domes-
12 tic health care providers and suppliers, including do-
13 mestic commercial health care providers, as deter-
14 mined by the Secretary, and sell at cost applicable
15 COVID–19 products to other commercial entities
16 and international entities. Amounts received from
17 the sale of such drugs shall be used for the activities
18 of the Office.

19 “(2) PROVISION OF APPLICABLE DRUGS, BIO-
20 LOGICAL PRODUCTS AND DEVICES.—The Secretary
21 shall sell applicable drugs, biological products, and
22 devices produced under this section at a fair price to
23 other entities. Amounts received from the sale of
24 such drugs shall be used to replenish the national
25 strategic stockpile under section 319F–2.

1 “(d) OVERSIGHT OF CONTRACTS.—In the case of ap-
2 plicable COVID–19 products and applicable drugs, bio-
3 logical products, and devices manufactured via contracts,
4 the Inspector General of the Department of Health and
5 Human Services shall conduct a review of not fewer than
6 1 of every 3 contracts entered into under this section, and
7 of the entities entering into such contracts, to ensure that
8 the Office is issuing contracts under fair and reasonable
9 terms and conditions, including facilitating the procure-
10 ment by the Federal Government of applicable COVID–
11 19 products and applicable drugs, biological products, and
12 medical devices at fair and reasonable prices. The Inspec-
13 tor General shall make each such review public and, in
14 cases where such a review identifies unreasonable prices,
15 submit recommendations to Congress on how the Office
16 should improve its contracting systems to ensure reason-
17 able pricing.

18 “(e) REPORTS TO CONGRESS.—The Director shall
19 prepare and submit to the President, the Committee on
20 Health, Education, Labor, and Pensions of the Senate,
21 and the Committee on Energy and Commerce of the
22 House of Representatives, a monthly report during the
23 public health emergency declared by the Secretary under
24 section 319 on January 31, 2020, with respect to COVID–

1 19, and a final report 3 months after the public health
2 emergency has concluded, that includes—

3 “(1) an assessment of the major supply chain
4 challenges facing hospitals, medical providers, the
5 Federal government, State, local, and tribal govern-
6 ments, and the private sector in procuring drugs, bi-
7 ological products, devices, and personal protective
8 equipment to combat and prevent the spread of
9 COVID-19; and

10 “(2) a description of the status of all drugs, bi-
11 ological products, devices, active pharmaceutical in-
12 gredients, and personal protective equipment for
13 which manufacturing has been authorized under this
14 section, including drugs, biological products, devices,
15 active pharmaceutical ingredients, and personal pro-
16 tective equipment being manufactured, drugs, bio-
17 logical products, devices, active pharmaceutical in-
18 gredients, and personal protective equipment for
19 which the Office has submitted an application for
20 approval or a notification for clearance or classifica-
21 tion to the Food and Drug Administration but has
22 not yet received approval, clearance, or classification,
23 and drugs, biological products, devices, active phar-
24 maceutical ingredients, and personal protective
25 equipment for which the Office has received ap-

1 proval, clearance, or classification from the Food
 2 and Drug Administration but are not being manu-
 3 factured.

4 “(f) DEFINITIONS.—In this section:

5 “(1) APPLICABLE DRUG, BIOLOGICAL PRODUCT,
 6 OR DEVICE DEFINITION.—The term ‘applicable drug,
 7 biological product, or device’ means a drug (as de-
 8 fined in section 201(g) of the Federal Food, Drug,
 9 and Cosmetic Act), biological product (as defined in
 10 section 351(i) of the Public Health Service Act),
 11 combination product (as described in section 503(g)
 12 of the Federal Food, Drug, and Cosmetic Act), or
 13 device (as defined in section 201(h) of the Federal
 14 Food Drug and Cosmetic Act) for which an ap-
 15 proved application under section 505 or 515 of the
 16 Federal Food, Drug, and Cosmetic Act or section
 17 351 of the Public Health Service Act, or clearance
 18 under section 510(k) of the Federal Food, Drug,
 19 and Cosmetic Act, is in effect, and—

20 “(A) is included in the drug shortage list
 21 under section 506E of the Federal Food, Drug,
 22 and Cosmetic Act; or

23 “(B) is vulnerable to shortage.

24 “(2) APPLICABLE COVID–19 PRODUCT DEFINI-
 25 TION.—

1 “(A) IN GENERAL.—The term ‘applicable
2 COVID–19 product’ means a product that is
3 included on a list that the Secretary of Health
4 and Human Services, in consultation with the
5 Commissioner of Food and Drugs, the Assist-
6 ant Secretary for Preparedness and Response,
7 and the Director of the Centers for Disease
8 Control and Prevention, shall compile not later
9 than 2 weeks after the date of enactment of
10 this section and shall review and update, as
11 necessary, every 2 weeks of—

12 “(i) qualified pandemic or epidemic
13 products, as defined under section 319F–
14 3, that are—

15 “(I)(aa) drugs, biological prod-
16 ucts, and devices that are manufac-
17 tured, used, designed, developed,
18 modified, licensed or procured—

19 “(AA) to diagnose, mitigate,
20 prevent, treat, or cure COVID–
21 19; or

22 “(BB) to limit the harm the
23 COVID–19 pandemic might oth-
24 erwise cause;

1 “(bb) drugs, biological products,
2 and devices that are manufactured,
3 used, designed, developed, modified, li-
4 censed, or procured to diagnose, miti-
5 gate, prevent, treat, or cure a serious
6 or life-threatening disease or condition
7 caused by a product described in item
8 (aa); or

9 “(cc) drugs, biological products,
10 devices or technologies intended to en-
11 hance the use or effect of a drug, bio-
12 logical product, or device described in
13 item (aa) or (bb); and

14 “(ii) personal protective equipment,
15 including protective equipment for eyes,
16 face, head, and extremities, protective
17 clothing, respiratory devices, and protective
18 shields and barriers, used to protect people
19 from COVID–19 infection.

20 “(B) CONSULTATION.—In developing the
21 list described in subparagraph (A), the Sec-
22 retary shall consult with the Administrator of
23 the Federal Emergency Management Adminis-
24 tration and the Secretary of Defense to ensure
25 that, in instances where the President has en-

1 acted the Defense Production Act to produce
2 applicable COVID–19 products, the Office does
3 not replicate or overproduce products being de-
4 veloped under the Act.

5 “(3) NATIVE HEALTH PROGRAM.—The term
6 ‘Native health program’ shall include—

7 “(A) a program provided through the In-
8 dian Health Service;

9 “(B) any health program operated by—

10 “(i) an Indian tribe, or Tribal organi-
11 zation, as such terms are defined in section
12 4 of the Indian Self-Determination and
13 Education Assistance Act;

14 “(ii) an inter-tribal consortium, as de-
15 fined in section 501(a) of the Indian Self-
16 Determination and Education Assistance
17 Act; or

18 “(iii) an urban Indian organization, as
19 defined in section 4 of the Indian Health
20 Care Improvement Act; and

21 “(C) any health program provided through
22 a Native Hawaiian health care system, as de-
23 fined in section 12 of the Native Hawaiian
24 Health Care Improvement Act.

1 “(4) DOMESTIC HEALTH CARE PROVIDER.—The
2 term ‘domestic health care provider’ shall include the
3 direct support professional, home health, and per-
4 sonal care attendant workforce.

5 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
6 are authorized to be appropriated such sums as may be
7 necessary to carry out this section.”.

○