



555 12th St. NW, Ste. 1001
Washington, D.C. 20004

Via www.regulations.gov
and U.S. First Class Mail

July 21, 2021

The Honorable Janet L. Yellen
Secretary of the Treasury
RIN 1545-BQ10
Department of the Treasury
1500 Pennsylvania Avenue
Washington, DC 20220

The Honorable Martin J. Walsh
Secretary of Labor
RIN 1210-AC07, EBSA/OHPSCA
Department of Labor
200 Constitution Ave. NW, N-5653
Washington, DC 20210

The Honorable Xavier Becerra
Secretary of Health and Human Services
CMS-9905-NC
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

The Honorable Kiran Ahuja
Director
RIN 3206-AO27
Office of Personnel Management
1900 E Street NW
Washington, DC 20415

The Honorable Shalanda D. Young
Acting Director
Office of Management and Budget
725 17th Street NW
Washington, DC 20503

Dear Secretaries Yellen, Walsh, and Becerra, Director Ahuja, and Acting Director Young:

RE: OPM/Treasury/Labor/HHS Notice Titled "Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs," File Code CMS-9905-NC, 86 *Fed. Reg.* 32813 (June 23, 2021)

This letter presents comments of the National Federation of Independent Business (NFIB) in response to the "Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs" published in the *Federal Register* of June 23, 2021. As the Biden White House stated in a fact sheet on February 22, 2021, "[s]mall businesses account for 44 percent of U.S. GDP, create two-thirds of net new jobs, and employ nearly half of America's workers." As your agencies implement the extensive reporting requirements in section 204 in Division BB of the Consolidated Appropriations Act, 2021, please minimize regulatory burdens on small businesses as requested below (see material in boldface type below), so as to leave them with greater freedom to grow their businesses and create jobs.

NFIB is an incorporated nonprofit association representing small and independent business members across America. NFIB protects and advances the ability of Americans to own, operate, and grow their businesses and ensures that governments of the United States and the fifty states hear the voice of small business as they formulate public policies. Small and independent business owners often seek health insurance coverage for themselves and their families and seek to assist or encourage their employees to obtain coverage for themselves and their families.

1. Newly-Enacted Requirements to Report on Pharmacy Benefits and Drug Costs

Section 204 in Division BB of the Consolidated Appropriations Act, 2021 (Public Law 116-260, December 27, 2020) enacted new, substantially similar sections in the Public Health Service Act (PHSA) (sec. 2799A-10), the Employee Retirement Income Security Act (ERISA) (sec. 725), and the Internal Revenue Code (IRC) (sec. 9825) for reporting on pharmacy benefits and drug costs. The new sections require "a group health plan or health insurance issuer offering group or individual health insurance coverage (except for a church plan)" (sec. 2799A-10), "a group health plan (or health insurance coverage offered in connection with such a plan)" (sec. 725), and "a group health plan" (sec. 9825) to report annually to the Secretaries of Health and Human Services, Labor, and the Treasury ten data elements on pharmacy benefits and drug costs.

Under the new legislation, the ten reportable data elements are: (1) the beginning and end dates of the relevant plan year; (2) the number of enrollees, participants, or beneficiaries; (3) each State in which the plan or coverage is offered; (4) the 50 brand prescription drugs most frequently dispensed by pharmacies for claims paid by the plan or coverage, and the total number of paid claims for each such drug; (5) the 50 most costly prescription drugs with respect to the plan or coverage by total annual spending, and the annual amount spent by the plan or coverage for each such drug; (6) the 50 prescription drugs with the greatest increase in plan expenditures over the plan year preceding the plan year that is the subject of the report, and, for each such drug, the change in amounts expended by the plan or coverage in each such plan year; (7) total spending on health care services, broken down by the type of costs, including hospital costs, health care provider and clinical service costs, for primary care and specialty care separately, costs for prescription drugs, and other medical costs, including wellness services, and spending on prescription drugs, both by the health plan or coverage and by the enrollees, participants, and beneficiaries; (8) the average monthly premium paid by employers on behalf of enrollees, participants, and beneficiaries and by enrollees, participants, and beneficiaries; (9) any impact on premiums by rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers, with respect to prescription drugs prescribed to enrollees, participants, or beneficiaries, including the amounts so paid for each therapeutic class of drugs, and for each of the 25 drugs that yielded the highest amount of rebates and other remuneration from drug manufacturers during the plan year; and (10) any reduction in premiums and out-of-pocket costs associated with the rebates, fees, or other remuneration.

The provisions of law enacted by section 204 in Division BB of the Consolidated Appropriations Act, 2021, impose a heavy and costly burden of collecting and reporting a broad range of data. In implementing those provisions, your agencies should take special account of the needs of small businesses.

2. Congressional Policy for Agencies to Take Special Account of the Needs of Small Businesses

Congress has established by law a clear policy that federal agencies should consider the special needs of small businesses when the agencies issue regulations. In section 2(a)(4) of the Regulatory Flexibility Act (RFA) (Public Law 96-354, 5 U.S.C. 601 note), Congress declared that “the failure to recognize differences in the scale and resources of regulated entities has in numerous instances adversely affected competition in the marketplace, discouraged innovation and restricted improvements in productivity. . . .” Congress also noted in section 2(a)(6) of the RFA that “the practice of treating all regulated businesses, organizations, and governmental jurisdictions as equivalent may lead to inefficient use of regulatory agency resources, enforcement problems, and, in some cases, to actions inconsistent with the legislative intent of health, safety, environmental and economic welfare legislation. . . .” Accordingly, your agencies should take special account of the needs of America's small and independent businesses as they administer the reporting requirements enacted by section 204 in Division BB of the Consolidated Appropriations Act, 2021.

Small businesses cannot afford the lawyers, accountants, and recordkeeping clerks that larger companies use to decipher regulations and implement business systems necessary to comply with detailed reporting requirements of the kind imposed by section 204 in Division BB of the Consolidated Appropriations Act, 2021. Small businesses mostly engage in low-technology, do-it-yourself compliance, in which a business owner trying to keep the business afloat attempts to keep up with recordkeeping and reporting as much as the owner can. Thus, your agencies, in administering section 204, should focus on ways to mitigate the impact of the data collection and reporting requirements of that section on small businesses.

In light of the special needs of small businesses in relation to section 725 of ERISA, section 2799A-10 of the PHSA, and section 9825 of the IRC, NFIB requests actions by the Secretaries of Labor, Health and Human Services, and the Treasury, as set forth below.

3. Minimization of Burden on Small Businesses of Collection and Reporting of Data Required by Section 204 in Division BB of the Consolidated Appropriations Act, 2021

NFIB asks the Secretary of Labor to exempt small businesses (defined as having one hundred or fewer employees) in relation to their welfare benefit plans from section 725 of ERISA, as enacted by section 204 in Division BB of the Consolidated Appropriations Act, 2021, using the exemption authority granted by section 104(a)(3) of ERISA (29 U.S.C. 1024(a)(3)). NFIB also asks the Secretary of Health and Human Services and the Secretary of the Treasury to seek to identify similar statutory exemption authority and exercise it to exempt small businesses (defined

as having 100 or fewer employees) in relation to their welfare benefit plans from sections 2799A-10 of the PHSA and section 9825 of the IRC, respectively. If the Secretary of Health and Human Services or the Secretary of the Treasury, or both, cannot identify statutory authority to make such exemptions for small businesses, then NFIB asks that they seek legislation the President judges necessary and expedient to provide such authority and, until its enactment and exercise, adopt the following regulatory provision to minimize the burden that the statutory data collection and reporting requirements impose on small businesses:

Sec. __. __ Minimization of Collection and Reporting Burden on Small Businesses

(a) *Definition.* For purposes of this section, the term "small business" means any entity that (1) has a duty, for itself, or on behalf of or in relation to a group health plan, a health insurance issuer, an insurance coverage, enrollees, participants, or beneficiaries, to collect and report information under any or all of sections 2799A-10 of the Public Health Service Act, 725 of Employee Retirement Income Security Act, and 9825 of the Internal Revenue Code; and (2) has one hundred or fewer employees.

(b) *Duty of Third-Party Administrator or Health Insurance Issuer.* Any administrator under contract to or otherwise engaged by a small business to administer for that business or its employees a group health plan or health insurance coverage offered in connection with such a plan, or a health insurance issuer for such business or its employees in connection with such a plan, shall perform, on behalf of the small business, the recordkeeping and reporting functions with respect to such plan or coverage required by sections 2799A-10 of the Public Health Service Act, 725 of Employee Retirement Income Security Act, and 9825 of the Internal Revenue Code.

(c) *Good Faith Estimates.* In complying with paragraphs (a)(4), (5), (6), (7), (8), (9), and (10) of sections 2799A-10 of the Public Health Service Act, 725 of Employee Retirement Income Security Act, and 9825 of the Internal Revenue Code, a small business, or an entity or person reporting on its behalf, may report based on estimates made in good faith.

(d) *Willfulness State of Mind.* (1) If any enforcement action occurs for an alleged violation by a small business, or any owner, director, officer, member, manager, or employee thereof, of any or all of sections 2799A-10 of the Public Health Service Act, 725 of Employee Retirement Income Security Act, and 9825 of the Internal Revenue Code, the state of mind required for such violation is willfulness.

(2) In any proceeding to enforce (including by imposition of any administrative, civil, criminal or other penalty) against a small business, or any owner, director, officer, member, manager, or employee thereof, sections 2799A-10 of the Public Health Service Act, 725 of Employee Retirement Income Security Act, and 9825 of the Internal Revenue Code, the burdens of pleading, production

of evidence, and persuasion (including with respect to willfulness) shall rest with the department or agency concerned and the burden of persuasion shall require proof by clear and convincing evidence.

(f) Assistance with Compliance. (1) The department or agency concerned shall provide, upon request, assistance to a small business with respect to complying with the collection and reporting requirements of sections 2799A-10 of the Public Health Service Act, 725 of Employee Retirement Income Security Act, and 9825 of the Internal Revenue Code.

(2) The department or agency concerned shall take steps (including furnishing a fillable Portable Document Format (PDF) form on the department or agency website) to permit a small business to file in either electronic or paper format any report under sections 2799A-10 of the Public Health Service Act, 725 of Employee Retirement Income Security Act, and 9825 of the Internal Revenue Code.

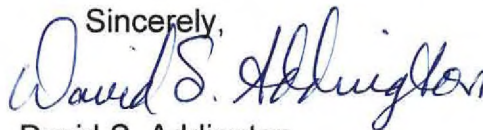
(3) Subject to the availability of appropriations, the department or agency concerned shall, upon request and in accordance with a simplified claim procedure, reimburse a small business for its cost of collecting and reporting information in accordance with sections 2799A-10 of the Public Health Service Act, 725 of Employee Retirement Income Security Act, and 9825 of the Internal Revenue Code.

* * * * *

The federal government must recognize that a mandate to report information to the government is not cost-free. When government mandates that businesses report information periodically to the government, the businesses must keep records of the information and report it, both of which cost the business time and money. Small businesses, in particular, face financial and practical difficulties in complying with the ever-growing number of government reporting requirements.

To help America's small businesses survive, grow, and create jobs, the Departments of the Treasury, Labor, and Health and Human Services, and the Offices of Management and Budget and Personnel Management, should, in their regulatory processes, seek to minimize the financial and other burdens imposed by regulations on America's small businesses. With the regulations your agencies issue to implement section 204 in Division BB of the Consolidated Appropriations Act, 2021, please minimize as requested the burden to small businesses of collecting and reporting data on pharmacy benefits and prescription drug costs.

Sincerely,



David S. Addington

Executive Vice President and General Counsel