

effect of the changes in the Medicare Part A premium will be a cost to voluntary enrollees (sections 1818 and 1818A of the Act) of about \$258 million.

#### C. Accounting Statement and Table

As required by OMB Circular A-4 (available at [www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf](http://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf)), in the Table below, we have prepared an accounting statement showing the total aggregate cost to enrollees paying premiums in CY 2022, compared to the amount that they paid in CY 2021. This amount will be about \$258 million. As stated in section IV of this notice, the CY 2022 premium of \$499 is approximately 5.9 percent higher than the CY 2021 premium of \$471. We estimate that approximately 721,000 enrollees will voluntarily enroll in Medicare Part A by paying the full premium. We estimate that over 90 percent of these individuals will have their Medicare Part A premium paid for by states, since they are enrolled in the QMB program. Furthermore, the CY 2022 reduced premium of \$274 is approximately 5.8 percent higher than the CY 2021 premium of \$259.

TABLE—ESTIMATED TRANSFERS FOR CY 2022 MEDICARE PART A PREMIUMS

Category	Transfers
Annualized Monetized Transfers.	\$258 million.
From Whom to Whom ....	Beneficiaries to Federal Government.

#### D. Regulatory Flexibility Act

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration's definition of a small business (having revenues of less than \$8.0 million to \$41.5 million in any 1 year). Individuals and states are not included in the definition of a small entity. This annual notice announces the Medicare Part A premiums for CY 2022 and will have an impact on certain Medicare beneficiaries. As a result, we are not preparing an analysis for the RFA because the Secretary has certified that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This annual notice announces the Medicare Part A premiums for CY 2022 and will have an impact on certain Medicare beneficiaries. As a result, we are not preparing an analysis for section 1102(b) of the Act, because the Secretary has certified that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

#### E. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately \$158 million. This notice does not impose mandates that will have a consequential effect of \$158 million or more on state, local, or tribal governments or on the private sector.

#### F. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This notice will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have federalism implications.

#### G. Congressional Review

This final action is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

*Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on November 10, 2021.*

Dated: November 12, 2021.

**Xavier Becerra,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2021-25052 Filed 11-12-21; 5:00 pm]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-8077-N]

RIN 0938-AU46

### Medicare Program; CY 2022 Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year (CY) 2022 under Medicare's Hospital Insurance Program (Medicare Part A). The Medicare statute specifies the formulae used to determine these amounts. For CY 2022, the inpatient hospital deductible will be \$1,556. The daily coinsurance amounts for CY 2022 will be: \$389 for the 61st through 90th day of hospitalization in a benefit period; \$778 for lifetime reserve days; and \$194.50 for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period.

**DATES:** The deductible and coinsurance amounts announced in this notice are effective on January 1, 2022.

**FOR FURTHER INFORMATION CONTACT:** Yaminee Thaker, (410) 786-7921 for general information and case mix analysis.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 1813 of the Social Security Act (the Act) provides for an inpatient hospital deductible to be subtracted from the amount payable by Medicare for inpatient hospital services furnished to a beneficiary. It also provides for certain coinsurance amounts to be subtracted from the amounts payable by Medicare for inpatient hospital and extended care services. Section 1813(b)(2) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary) to determine and publish each year the

amount of the inpatient hospital deductible and the hospital and extended care services coinsurance amounts applicable for services furnished in the following calendar year (CY).

## II. Computing the Inpatient Hospital Deductible for CY 2022

Section 1813(b) of the Act prescribes the method for computing the amount of the inpatient hospital deductible. The inpatient hospital deductible is an amount equal to the inpatient hospital deductible for the preceding CY, adjusted by our best estimate of the payment-weighted average of the applicable percentage increases (as defined in section 1886(b)(3)(B) of the Act) used for updating the payment rates to hospitals for discharges in the fiscal year (FY) that begins on October 1 of the same preceding CY, and adjusted to reflect changes in real case-mix. The adjustment to reflect real case-mix is determined on the basis of the most recent case-mix data available. The amount determined under this formula is rounded to the nearest multiple of \$4 (or, if midway between two multiples of \$4, to the next higher multiple of \$4).

Under section 1886(b)(3)(B)(i)(XX) of the Act, the percentage increase used to update the payment rates for FY 2022 for hospitals paid under the inpatient prospective payment system is the market basket percentage increase, otherwise known as the market basket update, reduced by an adjustment based on changes in the economy-wide productivity (the multifactor productivity (MFP) adjustment) (see section 1886(b)(3)(B)(xi)(II) of the Act). Under section 1886(b)(3)(B)(viii) of the Act, for FY 2022, the applicable percentage increase for hospitals that do not submit quality data as specified by the Secretary is reduced by one quarter of the market basket update. We are estimating that after accounting for those hospitals receiving the lower market basket update in the payment-weighted average update, the calculated deductible will not be affected, since the majority of hospitals submit quality data and receive the full market basket update. Section 1886(b)(3)(B)(ix) of the Act requires that any hospital that is not a meaningful electronic health record (EHR) user (as defined in section 1886(n)(3) of the Act) will have three-quarters of the market basket update reduced by 100 percent for FY 2017 and each subsequent FY. We are estimating that after accounting for these hospitals receiving the lower market basket update, the calculated deductible will not be affected, since the majority of hospitals are meaningful EHR users and

are expected to receive the full market basket update.

Under section 1886 of the Act, the percentage increase used to update the payment rates (or target amounts, as applicable) for FY 2022 for hospitals excluded from the inpatient prospective payment system is as follows:

- The percentage increase for long term care hospitals is the market basket percentage increase reduced by the MFP adjustment (see section 1886(m)(3)(A) of the Act). In addition, these hospitals may also be impacted by the quality reporting adjustments and the site-neutral payment rates (see sections 1886(m)(5) and 1886(m)(6) of the Act).

- The percentage increase for inpatient rehabilitation facilities is the market basket percentage increase reduced by a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act. In addition, these hospitals may also be impacted by the quality reporting adjustments (see section 1886(j)(7) of the Act).

- The percentage increase used to update the payment rate for inpatient psychiatric facilities is the market basket percentage increase reduced by the MFP adjustment (see section 1886(s)(2)(A)(i) of the Act). In addition, these hospitals may also be impacted by the quality reporting adjustments (see section 1886(s)(4) of the Act).

- The percentage increase used to update the target amounts for other types of hospitals that are excluded from the inpatient prospective payment system and that are paid on a reasonable cost basis, subject to a rate-of-increase ceiling, is the inpatient prospective payment system operating market basket percentage increase, which is described at section 1886(b)(3)(B)(ii)(VIII) of the Act and 42 CFR 413.40(c)(3). These other types of hospitals include cancer hospitals, children's hospitals, extended neoplastic disease care hospitals, and hospitals located outside the 50 states, the District of Columbia, and Puerto Rico.

The inpatient prospective payment system market basket percentage increase for FY 2022 is 2.7 percent and the MFP adjustment is 0.7 percentage point, as announced in the final rule that appeared in the **Federal Register** on August 13, 2021, entitled, "Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals; Changes to Medicaid

Provider Enrollment; and Changes to the Medicare Shared Savings Programs" (86 FR 45613). Therefore, the percentage increase for hospitals paid under the inpatient prospective payment system that submit quality data and are meaningful EHR users is 2.0 percent (that is, the FY 2022 market basket update of 2.7 percent less the MFP adjustment of 0.7 percentage point). The average payment percentage increase for hospitals excluded from the inpatient prospective payment system is 2.07 percent. This average includes long term care hospitals, inpatient rehabilitation facilities, and other hospitals excluded from the inpatient prospective payment system. Weighting these percentages in accordance with payment volume, our best estimate of the payment-weighted average of the increases in the payment rates for FY 2022 is 2.01 percent.

To develop the adjustment to reflect changes in real case-mix, we first calculated an average case-mix for each hospital that reflects the relative costliness of that hospital's mix of cases compared to those of other hospitals. We then computed the change in average case-mix for hospitals paid under the Medicare inpatient prospective payment system in FY 2021 compared to FY 2020. (We excluded from this calculation hospitals whose payments are not based on the inpatient prospective payment system because their payments are based on alternate prospective payment systems or reasonable costs.) We used Medicare bills from prospective payment hospitals that we received as of August 2021. These bills represent a total of about 6.4 million Medicare discharges for FY 2021 and provide the most recent case-mix data available at this time. Based on these bills, the change in average case-mix in FY 2021 is 2.9 percent. Based on these bills and past experience, we expect the overall case mix change to be 2.9 percent as the year progresses and more FY 2021 data become available.

Section 1813 of the Act requires that the inpatient hospital deductible be adjusted only by that portion of the case mix change that is determined to be real. Real case-mix is that portion of case-mix that is due to changes in the mix of cases in the hospital and not due to coding optimization. COVID-19 has complicated the determination of real case-mix increase. COVID 19 cases typically have higher-weighted MS DRGs which would cause a real increase in case-mix while hospitals have experienced a reduction in lower-weighted cases which would also cause a real increase in case-mix. In addition, care that was deferred in 2020 could be

more costly in 2021 causing an increase in real case-mix. Due to the uncertainty we are assuming that all of the recently observed care is not due to coding optimization and hence all of the 2.9 percent is real.

Thus, the estimate of the payment-weighted average of the applicable percentage increases used for updating the payment rates is 2.01 percent, and the real case-mix adjustment factor for the deductible is 2.9 percent. Therefore, using the statutory formula as stated in section 1813(b) of the Act, we calculate the inpatient hospital deductible for services furnished in CY 2022 to be \$1,556. This deductible amount is determined by multiplying \$1,484 (the inpatient hospital deductible for CY 2021 (85 FR 71916)) by the payment-weighted average increase in the

payment rates of 1.0201 multiplied by the increase in real case-mix of 1.029, which equals \$1,558 and is rounded to \$1,556.

**III. Computing the Inpatient Hospital and Extended Care Services Coinsurance Amounts for CY 2022**

The coinsurance amounts provided for in section 1813 of the Act are defined as fixed percentages of the inpatient hospital deductible for services furnished in the same CY. The increase in the deductible generates increases in the coinsurance amounts. For inpatient hospital and extended care services furnished in CY 2022, in accordance with the fixed percentages defined in the law, the daily coinsurance for the 61st through 90th day of hospitalization in a benefit

period will be \$389 (one-fourth of the inpatient hospital deductible as stated in section 1813(a)(1)(A) of the Act); the daily coinsurance for lifetime reserve days will be \$778 (one-half of the inpatient hospital deductible as stated in section 1813(a)(1)(B) of the Act); and the daily coinsurance for the 21st through 100th day of extended care services in a skilled nursing facility (SNF) in a benefit period will be \$194.50 (one-eighth of the inpatient hospital deductible as stated in section 1813(a)(3) of the Act).

**IV. Cost to Medicare Beneficiaries**

Table 1 summarizes the deductible and coinsurance amounts for CYs 2021 and 2022, as well as the number of each that is estimated to be paid.

TABLE 1—MEDICARE PART A DEDUCTIBLE AND COINSURANCE AMOUNTS FOR CYs 2021 AND 2022

Type of cost sharing	Value		Number paid (in millions)	
	2021	2022	2021	2022
Inpatient hospital deductible .....	\$1,484	\$1,556	6.11	6.43
Daily coinsurance for 61st–90th day .....	371	389	1.37	1.44
Daily coinsurance for lifetime reserve days .....	742	778	0.69	0.72
SNF coinsurance .....	185.50	194.50	29.69	28.63

The estimated total increase in costs to beneficiaries is about \$1,100 million (rounded to the nearest \$10 million) due to: (1) The increase in the deductible and coinsurance amounts; and (2) the increase in the number of deductibles and daily coinsurance amounts paid. We determine the increase in cost to beneficiaries by calculating the difference between the 2021 and 2022 deductible and coinsurance amounts multiplied by the estimated increase in the number of deductible and coinsurance amounts paid.

**V. Waiver of Proposed Rulemaking**

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment prior to a rule taking effect in accordance with section 1871 of the Act and section 553(b) of the Administrative Procedure Act (APA). Section 1871(a)(2) of the Act provides that no rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under Medicare shall take effect unless it is promulgated through notice and comment rulemaking. Unless there is a

statutory exception, section 1871(b)(1) of the Act generally requires the Secretary to provide for notice of a proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment before establishing or changing a substantive legal standard regarding the matters enumerated by the statute. Similarly, under 5 U.S.C. 553(b) of the APA, the agency is required to publish a notice of proposed rulemaking in the **Federal Register** before a substantive rule takes effect. Section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act usually require a 30-day delay in effective date after issuance or publication of a rule, subject to exceptions. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the advance notice and comment requirement and the delay in effective date requirements. Sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act also provide exceptions from the notice and 60-day comment period and the 30-day delay in effective date. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act expressly authorize an agency to dispense with notice and comment rulemaking for good cause if the agency makes a finding that notice and comment procedures are impracticable,

unnecessary, or contrary to the public interest.

The annual inpatient hospital deductible and the hospital and extended care services coinsurance amounts announcement set forth in this notice does not establish or change a substantive legal standard regarding the matters enumerated by the statute or constitute a substantive rule which would be subject to the notice requirements in section 553(b) of the APA. However, to the extent that an opportunity for public notice and comment could be construed as required for this notice, we find good cause to waive this requirement.

Section 1813(b)(2) of the Act requires publication of the inpatient hospital deductible and the hospital and extended care services coinsurance amounts between September 1 and September 15 of the year preceding the year to which they will apply. Further, the statute requires that the agency determine and publish the inpatient hospital deductible and hospital and extended care services coinsurance amounts for each CY in accordance with the statutory formulae, and we are simply notifying the public of the changes to the deductible and coinsurance amounts for CY 2022. We have calculated the inpatient hospital deductible and hospital and extended

care services coinsurance amounts as directed by the statute; the statute establishes both when the deductible and coinsurance amounts must be published and the information that the Secretary must factor into the deductible and coinsurance amounts, so we do not have any discretion in that regard. We find notice and comment procedures to be unnecessary for this notice and we find good cause to waive such procedures under section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act, if such procedures may be construed to be required at all. Through this notice, we are simply notifying the public of the updates to the inpatient hospital deductible and the hospital and extended care services coinsurance amounts, in accordance with the statute, for CY 2022. As such, we also note that even if notice and comment procedures were required for this notice, for the reasons stated above, we would find good cause to waive the delay in effective date of the notice, as additional delay would be contrary to the public interest under section 1871(e)(1)(B)(ii) of the Act. Publication of this notice is consistent with section 1813(b)(2) of the Act, and we believe that any potential delay in the effective date of the notice, if such delay were required at all, could cause unnecessary confusion both for the agency and Medicare beneficiaries.

## VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

## VII. Regulatory Impact Analysis

Although this notice does not constitute a substantive rule, we nevertheless prepared this Regulatory Impact Analysis section in the interest of ensuring that the impacts of this notice are fully understood.

### A. Statement of Need

This notice announces the Medicare Part A inpatient hospital deductible and associated coinsurance amounts for hospital and extended care services applicable for care provided in CY 2022, as required by section 1813 of the Act. It also responds to section 1813(b)(2) of the Act, which requires the Secretary to provide for publication of these amounts in the **Federal Register** between September 1 and September 15 of the year preceding the year to which

they will apply. As this statutory provision prescribes a detailed methodology for calculating these amounts, we do not have the discretion to adopt an alternative approach on these issues.

### B. Overall Impact

We have examined the impacts of this notice as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). Although we do not consider this notice to constitute a substantive rule, based on our estimates, OMB’s Office of Information and Regulatory Affairs has determined this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory

Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). As stated in section IV of this notice, we estimate that the total increase in costs to beneficiaries associated with this notice is about \$1,100 million due to: (1) The increase in the deductible and coinsurance amounts; and (2) the increase in the number of deductibles and daily coinsurance amounts paid.

### C. Accounting Statement and Table

As required by OMB Circular A–4 (available at [www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf](http://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf)), in Table 2, we have prepared an accounting statement showing the estimated total increase in costs to beneficiaries of about \$1,100 million, which is due to the increase in the deductible and coinsurance amounts, and the increase in the number of deductibles and daily coinsurance amounts paid. As stated in section IV of this notice, we determined the increase in cost to beneficiaries by calculating the difference between the 2021 and 2022 deductible and coinsurance amounts multiplied by the estimated increase in the number of deductible and coinsurance amounts paid.

TABLE 2—ESTIMATED TRANSFERS FOR CY 2022 DEDUCTIBLE AND COINSURANCE AMOUNTS

Category	Transfers
Annualized Monetized Transfers.	\$1,100 million.
From Whom to Whom ....	Beneficiaries to Providers.

### D. Regulatory Flexibility Act

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration’s definition of a small business (having revenues of less than \$8.0 million to \$41.5 million in any 1 year). Individuals and states are not included in the definition of a small entity. This annual notice announces the Medicare Part A deductible and coinsurance amounts for CY 2022 and will have an impact on the Medicare beneficiaries. As a result, we are not preparing an analysis for the RFA because the Secretary has certified that

this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This annual notice announces the Medicare Part A deductible and coinsurance amounts for CY 2022 and will have an impact on the Medicare beneficiaries. As a result, we are not preparing an analysis for section 1102(b) of the Act because the Secretary has certified that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

#### *E. Unfunded Mandates Reform Act*

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately \$158 million. This notice does not impose mandates that will have a consequential effect of \$158 million or more on state, local, or tribal governments or on the private sector.

#### *F. Federalism*

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This notice will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have federalism implications.

#### *G. Congressional Review*

This final action is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

*Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on November 10, 2021.*

Dated: November 12, 2021.

**Xavier Becerra,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2021-25051 Filed 11-12-21; 5:00 pm]

**BILLING CODE 4120-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Administration for Children and Families**

#### **Submission for OMB Review; Head Start Evaluation of a Trauma-Informed Care Program (New Collection)**

**AGENCY:** Office of Head Start, Administration for Children and Families, HHS.

**ACTION:** Request for public comment.

**SUMMARY:** The Office of Head Start, Administration for Children and Families (ACF), is proposing to collect data for a new evaluation of a trauma-informed care program that will include a small randomized controlled trial across 10 sites within Head Start Region V. The goals of the project are to identify the implementation supports and methods needed to enable teachers to effectively implement Trauma-Informed Care in early care and education programs, and to evaluate its outcomes. Information collected will be used to inform ongoing training and technical assistance (TTA) work provided by the Head Start Centers, particularly decisions regarding allocation of TTA resources. More generally, results may inform OHS guidance around social-emotional programming.

**DATES:** *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. You can also obtain copies of the proposed collection of information by emailing [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). Identify all emailed requests by the title of the information collection.

#### **SUPPLEMENTARY INFORMATION:**

*Description:* The National Center on Health, Behavioral Health, and Safety, in partnership with Child Trends and the Center for Childhood Resilience at the Anne & Robert H. Lurie Children’s Hospital of Chicago (Lurie), will conduct information collection activities across 10 sites within Head Start Region V as part of a small randomized controlled trial of the Ready to Learn through Relationships (RLR) program, a trauma-informed Framework and Toolkit designed to promote resilience in young children. In this evaluation, sites will be matched on a number of factors that may be related to implementation and randomized to either a low- or high-intensity TTA condition. The low-intensity condition will receive 4 hours of training, a “toolkit” of activity-based handouts, and access to virtual TA office hours. The high-intensity condition will include 4 hours of additional training on use of the toolkit modules, 6 hours of implementation support, and monthly classroom coaching.

Region V Head Start programs that choose to voluntarily participate in the RLR program will be asked to complete a number of implementation and outcomes measures and participate in other evaluation activities. Data collection will involve virtual semi-structured interviews and focus groups at the end of the evaluation period, web-based surveys (pre and post), a monthly web-based log of coaching activities completed, and repeated teacher reports of practices throughout the day on a mobile app during 5 weeks across the school year.

The information to be collected focuses on teacher practices for supporting children’s social-emotional development and on training and implementation factors that may enhance these practices, which is directly relevant to Head Start’s mission. Information obtained will be shared with Regional TTA providers and site administrators to inform their ongoing and future TTA work. More specifically, results of the evaluation will identify the extent to which more intensive TTA with ongoing coaching and on-site expert consultation enhances teacher practice beyond a lower-intensity TTA approach. Additionally, data are expected to identify implementation factors that may enhance outcomes at both the level of the teacher and Head Start Centers.

*Respondents:* All early childhood centers in Head Start Region V that meet inclusion criteria will be invited to submit application forms to participate in the evaluation, and approximately 10