

(SEPs) for exceptional conditions. Section 402 of the CAA extends immunosuppressive drug coverage under Medicare Part B for certain individuals whose Medicare entitlement based on end-stage renal disease (ESRD) would otherwise end 36 months after the month in which they received a successful kidney transplant. Together, these proposals not only implement provisions of the CAA, but also support President Biden's *Executive Order on Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage*, *Executive Order on Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government*, *Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* and *Executive Order On Strengthening Medicaid and the Affordable Care Act* by eliminating potentially confusing coverage waiting periods, allowing CMS and the Social Security Administration to remedy missed enrollment periods by allowing for SEPs for exceptional conditions and extending coverage of Medicare Savings Programs (MSPs) to include payment of premiums and cost-sharing for a new immunosuppressive drug coverage under Part B.

Separately, this rule would delete references to specific Medicare forms from the text of existing regulations at §§ 406.7 and 407.11 in order to provide greater administrative flexibility. Finally, this proposed rule would update the various federal regulations that affect a state's payment of Medicare Part A and B premiums for beneficiaries enrolled in the Medicare Savings Programs and other Medicaid eligibility groups.

DATES: To be assured consideration, comments must be received at one of the addresses provided, no later than 5 p.m. on [Insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, refer to file code CMS-4199-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-4199-P,
P.O. Box 8013,
Baltimore, MD 21244-4199

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-4199-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850. [Note: This zip code is for express mail or courier delivery only. This zip code specifies the agency's physical location.]

I. Summary

A. Beneficiary Enrollment Simplification in Medicare Parts A and B - Overview

1. Background

Medicare is a Federal program to provide health insurance for people age 65 and older, and those under 65 with certain disabilities or ESRD. Medicare consists of four distinct parts, commonly referred to as Medicare Parts A, B, C and D. Medicare Part A, sometimes referred to as hospital insurance (HI), covers inpatient hospital services, skilled nursing care, hospice care, and some home health services. Individuals must meet certain conditions to be entitled to Part A. Medicare Part B, or supplementary medical insurance (SMI), is an optional benefit that helps cover medically necessary services and supplies like physicians' services, durable medical equipment, outpatient care, and other medical services that Part A does not cover, including many preventive services. Together, Medicare Parts A and B comprise "original" or "traditional" Medicare. Most beneficiaries are automatically enrolled in Part A and Part B by the Social Security Administration (SSA) or the Railroad Retirement Board when they turn 65. In addition, if an individual has been receiving Social Security or Railroad Retirement Disability benefits for 24 months, they will automatically be enrolled by SSA or the Railroad Retirement Board in Medicare Parts A and B.

The first opportunity individuals have to enroll in Part B is during their initial enrollment period (IEP). The IEP is a 7-month period that usually begins 3 months before the month in which an eligible individual turns 65 and ends 3 months after the first month of eligibility. The next opportunity for eligible individuals who do not enroll in Part B during their IEP to enroll in Part B, if they choose to do so, is in the general enrollment period (GEP) which runs from January 1st through March 31st each year. Currently, an individual's entitlement (coverage

period effective date) under Part B depends on the enrollment period and the month in which the individual enrolls, according to the requirements in sections 1837 and 1838 of the Social Security Act (the Act).

For those who enroll in Medicare Part B during any of the first 3 months of their IEP, coverage is effective the first month they become eligible for Medicare (such as age 65 or the 25th month of entitlement to monthly Social Security or railroad retirement benefits based on disability). However, for those who enroll in any of the last 4 months of their IEP, their coverage becomes effective after their month of enrollment, with the effective date of coverage varying depending on the month in which they enroll.

For individuals subject to the current requirements at 42 CFR 407.10, and who enroll during the GEP, coverage is effective the July 1 following the month in which the individual enrolls.

Example. An individual's 65th birthday is April 10 and they first meet the eligibility requirements for enrollment April 1. The individual's initial enrollment period would extend from January through July in the year they turn 65. The month in which the individual enrolls in Part B determines the month in which their period of entitlement would begin, as follows:

IEP Enrollments During a Month Before January 1, 2023	Entitlement begins on—
January	April 1 (month eligibility requirements first met).
February	April 1.
March	April 1.
April	May 1 (month following month of enrollment).
May	July 1 (second month after month of enrollment).
June	September 1 (third month after month of enrollment).
July	October 1 (third month after month of enrollment).

For individuals subject to the current requirements at 42 CFR 407.10, and who enroll during the GEP, coverage is effective the July 1 following the month in which he or she enrolls.

2. Proposal Summary

Section 120 of the Consolidated Appropriations Act, 2021 (CAA), Public Law (Pub. L.) 116-260, Division CC, title I, section 120 (December 27, 2020), modified the requirements in section 1838 of the Act, pertaining to individuals enrolling in Part B after not being automatically enrolled, or who are re-enrolling in Part B after disenrollment. Specifically, the CAA revised sections 1838(a)(2)(C), 1838(a)(3)(A), and 1838(a)(2)(D) of the Act to provide that for individuals who become eligible for Medicare on or after January 1, 2023, and enroll in Part B during the last 3 months of their IEP, entitlement would begin the first day of the month following the month in which they enroll.

These changes enacted under section 120 of the CAA will result in coverage under Part B that becomes effective sooner after an individual enrolls during the IEP, deemed IEP, or GEP. We expect these changes will simplify the enrollment process and reduce gaps in health care coverage, and make it easier for affected beneficiaries to understand the effective date of their Medicare coverage. We are proposing conforming changes to our regulations at 42 CFR part 407 to implement these Part B changes. In addition, while the statutory provisions of section 120 of the CAA primarily affect individuals enrolling in Part B, those changes will also affect the requirements applicable to the limited number of individuals enrolling in Part A who are not entitled to premium-free Part A. We are proposing conforming modifications to our regulations at 42 CFR part 406 to reflect those Part A changes.

Additionally, section 120 of the CAA established new section 1837(m) of the Act, which provides authority for the Secretary of the Department of Health and Human Services (HHS) (the Secretary) to establish SEPs for individuals who are eligible to enroll in Medicare and meet such exceptional conditions as the Secretary may provide, effective January 1, 2023. Corresponding

changes in sections 1838(g) and 1839(b) of the Act provide the Secretary the discretion to determine the effective date of entitlement for individuals who enroll under an SEP for exceptional conditions, and exempt individuals enrolling under such an SEP from being subject to a late enrollment penalty (LEP), respectively. We are proposing to establish several SEPs for exceptional conditions in this proposed rule, and would incorporate those SEPs in our regulations under 42 CFR parts 406 and 407.

B. Extended Coverage of Immunosuppressive Drugs for Certain Kidney Transplant Patients --

Overview

1. Background

End-stage renal disease (ESRD) is a medical condition in which a person's kidneys cease functioning permanently, leading to the need for a regular course of long-term dialysis or a kidney transplant to maintain life. A kidney transplant is ultimately considered the best treatment for ESRD. Section 226A of the Act includes a provision that enables certain individuals diagnosed with ESRD to be entitled to Medicare, regardless of age. If an individual with ESRD applies for Medicare and is entitled to Medicare Part A and eligible for Part B benefits, Medicare provides coverage for all covered medical services, not only those related to the kidney failure condition. When an individual receives a successful kidney transplant, Medicare coverage extends for 36 months after the month in which the individual receives the transplant. Currently, after the 36th month, Medicare coverage ends unless the individual is eligible for Medicare on another basis, such as age or disability.

Medicare Part B covers medical and other health services including, as specified in section 1861(s)(2)(J) of the Act, prescription drugs used in immunosuppressive therapy furnished to an individual who receives an organ transplant for which Medicare payment is made. Kidney

transplant recipients must take immunosuppressive drugs to help prevent their immune systems from rejecting the transplanted kidney. If a transplanted kidney is rejected, the individual would revert to ESRD status and again need dialysis treatment or another transplant.

Under current law, Medicare Part B beneficiaries have coverage for such immunosuppressive drug therapy for as long as they remain eligible for and enrolled in Medicare Part B. However, section 226A(b)(2) of the Act currently requires that entitlement to Medicare Part A and eligibility to enroll under Part B for ESRD beneficiaries ends with the 36th month after the month in which the individual receives a successful kidney transplant (see also 42 CFR 406.13(f)(2)).

2. Proposal Summary

Section 402 of the CAA amended sections 226A(b)(2) (and made conforming changes to sections 1836, 1837, 1838, 1839, 1844, 1860D-1, 1902, and 1905 of the Act) to make certain individuals eligible for enrollment under Medicare Part B solely for purposes of coverage of immunosuppressive drugs described in section 1861(s)(2)(J) of the Act. Effective January 1, 2023, this provision would allow certain individuals whose Medicare entitlement based on ESRD would otherwise end after a successful kidney transplant to continue enrollment under Medicare Part B only for the coverage of immunosuppressive drugs described in section 1861(s)(2)(J) of the Act. These individuals would not receive Medicare coverage for any other items or services (under either Part A or Part B), and would only be eligible for immunosuppressive drug coverage under Part B if they are not enrolled in certain other types of coverage, as described in “Eligibility for the Part B-ID Benefit” (section II.B.2.b. this proposed rule). Section 402 of the CAA also amended the Medicare Savings Programs (MSPs) under sections 1905(p)(1)(A) and 1902(a)(10)(E) of the Act to pay the Part B premiums and in some

cases the costs of the Part B deductible and coinsurance for immunosuppressive drug coverage for certain low-income individuals.

C. Simplifying Regulations Related to Medicare Enrollment Forms -- Overview

1. Background

Individuals who receive monthly Social Security or railroad retirement benefits at age 65 or have been entitled to monthly Social Security or railroad retirement benefits based on disability benefits for more than 24 months, are automatically entitled to Part A and do not have to file a separate application in order to enroll in premium-free Part A. These individuals are automatically enrolled (auto-enrolled) by the Social Security Administration or the Railroad Retirement Board into Part A when they reach age 65 or their 25th month of entitlement to Social Security or railroad retirement benefits based on disability. Individuals who become eligible for premium-free Medicare but who are not auto-enrolled, either because they have delayed receiving Social Security or railroad retirement benefits, or are not eligible for such benefits but are otherwise eligible to receive premium-free Medicare part A based on paying the Medicare payroll tax, must file a separate application to enroll in Medicare. Individuals who decide to collect Social Security benefits after they reach age 65, and thus did not get auto-enrolled in Medicare by virtue of receiving Social Security benefits, may use their application for Social Security benefits, as defined in 42 CFR 400.200, to apply for Medicare if they are eligible for Part A at that time. Individuals may also separately request enrollment in Part B by answering the Part B enrollment questions on an application for monthly Social Security retirement or spousal benefits. As an alternative, individuals may enroll in Part B by signing a simple statement of request, if they are eligible to enroll at that time.

Currently, there are a total of seven enrollment forms for traditional Medicare— two

enrollment forms for Part A and five enrollment forms for Part B, in §§ 406.7 and 407.11, respectively. Medicare enrollment forms are available to individuals via mail from CMS or SSA, downloadable via the CMS and SSA websites, or in person at SSA field offices. CMS and SSA periodically review the enrollment forms to determine if updates are necessary to comply with statutory, regulatory, or operational changes. Our regulations currently identify each form by name and provide a brief description of its uses.

2. Proposal Summary

We are proposing to remove references to individual enrollment forms from our regulations, including their titles and brief descriptions, to provide greater administrative flexibility in updating, adding, or removing forms in the future. We are also proposing to make technical edits to the text to state that an individual who files an application for monthly Social Security cash benefits as defined in § 400.200 also applies for Medicare entitlement if he or she is eligible for hospital insurance at that time.

D. Modernizing State Payment of Medicare Premiums -- Overview

1. Background

Since the implementation of the original Medicare program in 1966, section 1843 of the Act has provided states the option to enter into an “agreement” with the Federal government under which a state commits to enrolling certain Medicare-eligible Medicaid beneficiaries into Medicare Part B with the state paying the Part B premiums on their behalf. Section 1903(a)(1) and (b) of the Act authorize federal financial participation (FFP) for such state payment of Part B premiums for certain dually eligible individuals. We have historically referred to this process as

“state buy-in.” All 50 states and the District of Columbia have buy-in agreements for Part B¹ with the Secretary.

States pay Medicare Part B premiums for approximately 10 million individuals and Part A premiums for approximately 700,000 individuals each year who are not entitled to Part A without a premium. For an individual who is eligible for but not yet enrolled in Medicare, state buy-in serves to both enroll the individual in Medicare and enable the Federal Government to bill the state for the new beneficiary’s Medicare premiums. For an individual who is already enrolled in Medicare, state buy-ins enable the Federal Government to bill the state for the individual’s Medicare premiums and stop collecting the premiums through deductions from the beneficiary’s monthly Social Security (Old Age Insurance or Disability benefits or Supplemental Security Income), Railroad Retirement Board (RRB), or Office of Personnel Management (OPM) benefits, or through CMS direct billing.

The impact of state buy-in is significant for many beneficiaries. Low-income individuals who receive assistance with Medicare premiums save critical funds to use for other necessities, including food and housing. Upon state buy-in, individuals who were paying the Medicare premiums through deductions from their Social Security benefits see a notable increase in their monthly social security checks (the standard Part B premium is \$170.10 per month in 2022), and individuals eligible but not enrolled in Medicare are able to enroll in the program and access Medicare services.

2. Proposal Summary

We are proposing changes to the state buy-in that would better align the regulations with federal statute, policy and operations that have evolved over time, including revising the

¹ Thirty-seven states (including the District of Columbia) also have buy-in agreements for Part A.

regulations to provide that approved State plan provisions governing the buy-in process constitute a State's buy-in agreement and limiting retroactive Medicare Part B premium liability for states for full-benefit dually eligible beneficiaries. By clarifying and streamlining existing requirements, these proposals would improve the customer service experience of dually eligible beneficiaries pursuant to the *Executive Order on Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government* and promote access to affordable health coverage and essential medical treatment and improve health equity for underserved populations consistent with the *Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*.

II. Provisions of the Proposed Rule

A. Proposals for Beneficiary Enrollment Simplification (§§ 406.21, 406.22, 406.27, 406.33, 406.34, 407.22, 407.25, and 408.24)

1. Effective Dates of Entitlement

While the majority of individuals are automatically enrolled in Medicare Parts A and B upon reaching age 65 or when they have been entitled to monthly Social Security or railroad retirement benefits based on disability for more than 24 months, certain individuals are required to take active steps to enroll. Specifically, individuals who are eligible for, but not receiving, monthly Social Security benefits under section 202 of the Act or qualified RRB benefits when they turn 65, are not auto-enrolled because they have elected not to start receiving their Social Security or RRB benefits and have not filed an application for Social Security or RRB benefits and must take separate action to apply for Medicare. Certain individuals who are entitled to premium free Part A through government employment, but are not eligible for Social Security or RRB benefits also have to take action to apply for Medicare. Individuals may apply for Part A at

any time, but can only apply for Part B during a specific enrollment period (IEP, GEP, or SEP). Further, under section 1818 of the Act, certain individuals who are not otherwise entitled to Part A but meet certain requirements, are eligible to enroll in Part A. These individuals are required to pay monthly premiums under section 1818(d) of the Act, and this benefit is frequently referred to as “premium Part A.” These individuals are required to take active steps to enroll in premium Part A and Part B.

As briefly described previously, the period during which these individuals are entitled to receive benefits under Medicare, also known as the coverage period, can vary depending on when the individual enrolls. The first opportunity individuals have to enroll in Part B is during their IEP. Section 1837(d) of the Act defines the IEP for most individuals who become eligible for Medicare on or after March 1, 1966. For these individuals, the IEP begins on the first day of the third month before the month the individual turns 65 and ends seven months later. Section 1837(d) of the Act also defines what is commonly referred to as the “deemed IEP.” When an individual fails to enroll during their IEP because of a belief, based on erroneous documentary evidence, that he or she had not yet attained age 65, section 1837(d) of the Act requires the Secretary to establish an IEP for such individual. Such individuals are considered “deemed” to have enrolled for purposes of section 1838(a)(3) of the Act, and these individuals are subject to entitlement periods consistent with those applied for individuals not subject to a deemed initial enrollment period under 42 CFR 407.14.

Eligible individuals who do not enroll in Part B during their IEP or deemed IEP, or who disenroll from Part B and wish to re-enroll, must generally do so during the GEP. The GEP is established under section 1837(e) of the Act, and is the period beginning on January 1 and ending on March 31 of each year. Section 1838(a) of the Act establishes the beginning of

entitlement for Part B for individuals who enroll in their IEP or GEP. According to the current requirements established under sections 1838(a)(2)(A) and 1838(a)(3)(A) of the Act for individuals who become eligible to enroll in Medicare under section 1836(a) of the Act before January 1, 2023, and enroll during the first 3 months of their IEP or deemed IEP, their entitlement would begin on the first day of the month they turn 65. For such individuals who enroll during the month in which they become eligible, sections 1838(a)(2)(B)(i) and 1838(a)(3)(B)(i) of the Act currently specify that their entitlement begins with the first day of the month following the month in which they enroll. For such individuals who enroll in the month after the month in which they satisfy the requirements of section 1836(a) of the Act, their entitlement would begin with the first day of the second month after the month in which they enroll under sections 1838(a)(2)(B)(ii) and 1838(a)(3)(B)(i) of the Act. For such individuals who enroll in Medicare during the last 2 months of their IEP or deemed IEP, their entitlement under Medicare would be effective beginning with the first day of the third month after the month in which he or she enrolls according to sections 1838(a)(2)(B)(iii) and 1838(a)(3)(B)(i) of the Act. Finally, for such individuals who enroll in Medicare under the GEP in a month beginning before January 1, 2023, sections 1838(a)(2)(D)(1) and 1838(a)(3)(B)(i) provide that their entitlement would begin with the first of July following their enrollment.

Section 120(a)(1) of the CAA revised the entitlement periods for individuals who enroll in Medicare Part B in the last 3 months of their IEP, deemed IEP, or during the GEP, beginning January 1, 2023. Specifically, the CAA modified section 1838 of the Act such that revised section 1838(a)(2)(C) and (a)(3)(B)(ii) of the Act provide that for a Medicare eligible individual who satisfies the requirements of section 1836(a) of the Act in a month beginning on or after January 1, 2023, and who enrolls in the month in which they satisfy those requirements, or in any

subsequent month of their IEP, the individual’s entitlement would begin with the first day of the month following the month of enrollment. The CAA also revised sections 1838(a)(2)(D)(ii) and 1838(a)(3)(B)(ii) of the Act to provide that for individuals who enroll during the GEP in a month beginning on or after January 1, 2023, their entitlement would begin with the first day of the month following the month in which they enroll.

We expect that these changes to the entitlement for individuals who enroll during their IEP or GEP are likely to increase access to continuous coverage under Medicare Part B, both by expediting these individuals’ entitlement dates and decreasing enrollees’ confusion about when their coverage becomes effective. Therefore, we anticipate this change having a positive impact on Medicare beneficiaries, including those in communities who may be disproportionately impacted by lack of continuous health coverage.

Enrolls in IEP:	Prior to 1/1/23 – Entitlement begins on:	On or After 1/1/23 – Entitlement begins on:
January	April 1 (month eligibility requirements first met).	April 1 (month eligibility requirements first met)
February	April 1.	April 1
March	April 1.	April 1
April	May 1 (month following month of enrollment).	May 1
May	July 1 (second month after month of enrollment).	June 1
June	September 1 (third month after month of enrollment).	July 1
July	October 1 (third month after month of enrollment).	August 1

As shown in the chart, the changes made to section 1838(a) of the Act according to section 120 of the CAA directly affect the requirements for individuals enrolling in Part B. However, these changes will also impact certain individuals enrolling in Part A. Section 1818(c) of the Act specifically requires in part that the provisions of section 1838 of the Act apply to individuals enrolling in premium Part A for purposes of determining the period of enrollment and other aspects of coverage. In light of this statute, the revised entitlement periods established in section 1838(a) of the Act will also apply to premium Part A enrollees.

Therefore, to implement the changes to 1838(a) of the Act, we are proposing to revise language in both 42 CFR part 406 (for premium Part A) and 42 CFR part 407 (for Part B).

Specifically, we propose the following to reflect changes related to the start of entitlement for premium Part A IEP enrollments:

- Section 406.22(a) would be revised to apply the existing requirements governing the entitlement period for individuals who are age 65 or older before January 1, 2023 who enroll in premium Part A during their IEP.
- Existing § 406.22(b) would be redesignated as paragraph (c). New paragraph (b) would lay out the entitlement dates for individuals who attained age 65 on or after January 1, 2023, and who enroll during their IEP, including a deemed IEP. Subparagraph (b)(1) would provide that for such individuals who enroll during the first 3 months of their IEP, entitlement begins with the first month of eligibility. Subparagraph (b)(2) would specify that if such an individual enrolls during the last 4 months of their IEP, entitlement would begin with the month following the month in which they enrolled.
- Newly redesignated § 406.22(c) would be revised to apply the existing entitlement date requirements for individuals under age 65 who became eligible for Medicare prior to January 1, 2023. For individuals who enroll during the first 3 months of their IEP, entitlement would begin with the first month of eligibility. If an individual enrolls during the month in which they first become eligible, entitlement would begin with following month. If an individual enrolls in the month following the month of eligibility, entitlement would begin with the second month after the month of enrollment. If the individual enrolls more than one month after the month of eligibility, entitlement would begin with the third month after the month of enrollment.

- New § 406.22(d) would set out the start dates for entitlement for individuals under age 65 who enroll in premium Part A on or after January 1, 2023. For individuals enrolling during the first 3 months of their IEP, entitlement would begin with the first month of eligibility. If an individual enrolls during the last 4 months of their IEP, their entitlement would begin with the following month.

We propose the following to reflect changes related to the start of entitlement for individuals enrolling in Part B during their IEP:

- We would revise section 407.25(a)(1) to apply the existing entitlement date requirements to individuals who first satisfy the Part B eligibility requirements before January 1, 2023 and enroll during their IEP or deemed IEP.

- Section 407.25(a)(2) would apply to individuals who first satisfy the Part B eligibility requirements on or after January 1, 2023. Entitlement for such individuals would begin with the first month of eligibility for enrollments made during the first 3 months of the IEP. We are proposing that § 407.25(a)(2)(ii) would specify that if such an individual enrolls during the last 4 months of their IEP, entitlement would begin with the month following the month in which they enroll.

Section 120(a)(1)(A) of the CAA also modified section 1838(a)(2) of the Act, to address the beginning of the entitlement for individuals enrolling during their GEP according to 1837(e) of the Act. We are proposing the following changes to reflect those requirements for individuals enrolling in premium Part A:

- Section 406.21(c)(3) would be revised to reflect the revised entitlement periods for individuals who enroll or reenroll during a GEP. Specifically, § 406.21(c)(3)(i) would require that for individuals who enroll or reenroll during a GEP prior to January 1, 2023, entitlement

would begin July 1st following their enrollment, consistent with section 1838(a)(2)(D)(i) of the Act and the existing entitlement date requirements. Section 406.21(c)(3)(ii) would require that for individuals who enroll or reenroll during a GEP on or after January 1, 2023, entitlement would begin on the first day of the month after the month of enrollment, consistent with section 1838(a)(2)(D)(ii) of the Act.

- Section 407.25(b)(1) would be revised to require that for individuals enrolling or reenrolling in Part B during a GEP before January 1, 2023, the current requirements governing the entitlement date would continue to apply. Specifically, revised § 407.25(b)(1) would state that for all such individuals enrolling or reenrolling during a GEP before April 1, 1981, or after September 30, 1981 and before January 1, 2023, entitlement would begin on July 1 of that calendar year.

- New § 407.25(b)(3) would require that for individuals who enroll or reenroll in Part B during a GEP on or after January 1, 2023, entitlement would begin the first day of the month following the month of enrollment.

We note that CMS would update all public facing materials to reflect date changes from any final rule. This would include updated information in CMS publications, on Medicare.gov, and in training materials.

2. Special Enrollment Periods for Exceptional Conditions

Under normal conditions, individuals who want to enroll in premium Part A, Part B, or both must submit a timely enrollment request during their IEP, the GEP, or an existing SEP for which they are eligible. Those who fail to enroll during their IEP may face a life-long penalty for late enrollment and a potential gap in coverage. Prior to the enactment of the CAA, CMS did not have broad authority to create SEPs based on exceptional conditions for enrollees in

Medicare Parts A and B.² Section 120(a)(2)(A) of the CAA established section 1837(m) of the Act to provide the Secretary with authority to establish SEPs for individuals who satisfy the requirements in paragraph (1) or (2) of section 1836(a) of the Act, and meet such exceptional conditions as the Secretary may provide, beginning January 1, 2023. Section 120 of the CAA also created section 1838(g) of the Act to provide the Secretary the discretion to determine the entitlement period for individuals who enroll pursuant to an SEP established according to section 1837(m) of the Act, in a manner that protects the continuity of health benefit coverage to the extent practicable. The CAA also modified section 1839(b) of the Act to exempt individuals who enroll pursuant to an SEP for exceptional conditions established under section 1838(m) of the Act, from paying an LEP. Section 1818(c) of the Act provides that individuals enrolling under premium Part A are generally afforded the same enrollment opportunities as those available under Part B, so our proposals would apply to both premium Part A and Part B, except where noted.

Several SEPs currently exist that permit individuals to enroll in premium Part A or Part B outside of the IEP or GEP. The existing SEPs are briefly described as follows:

- Sections 1837(i)(1) through (3) of the Act provide an SEP for certain individuals who are enrolled in a qualified group health plan (GHP) or large GHP (LGHP) at the time they first become eligible for Medicare and elect not to enroll (or to be deemed enrolled) in Medicare during their IEP.
- Section 1837(i)(4) of the Act establishes an SEP for certain workers who are eligible for disability benefits. Specifically, an SEP is available to covered individuals who are enrolled

² CMS has separate authority for Medicare Parts C and D under sections 1851(e)(4)(d) and 1860D-1(b)(3)(C) of the Act, respectively.

in a GHP (based on their own current or former employment or the current or former employment of a family member) at the time they first become eligible for Medicare, and who elect not to enroll (or be deemed enrolled) during their IEP, when their continuous enrollment in such GHP is involuntarily terminated, provided certain other requirements are met.

- The SEP for international volunteers, established under section 1837(k) of the Act, establishes an SEP for individuals serving as volunteers outside the United States at the time they first become eligible for Medicare, through a program covering at least a 12-month period, sponsored by a 501(c)(3) tax exempt organization, and who demonstrate health insurance coverage while serving in the program. These international volunteers are eligible for an SEP, if they elect not to enroll (or be deemed enrolled) under section 1837 of the Act during their IEP or terminate Medicare enrollment during a month in which they are serving in such program.

- Section 1837(l) of the Act establishes a 12-month SEP for certain individuals who are enrolled in TRICARE and become eligible to enroll in Part A on the basis of disability or ESRD status under sections 226(b) or 226A of the Act, respectively, but who elect not to enroll (or to be deemed enrolled) during their IEP.

We are proposing to establish new exceptional conditions SEPs under section 1837(m) of the Act in §§ 406.27 and 407.23 of the regulations for Medicare parts A and B, respectively. These SEPs would be available to individuals who have missed an enrollment period due to a covered exceptional condition. Specifically, individuals who miss an IEP, GEP, or another SEP, such as the GHP SEP, due to a covered exceptional condition, would be eligible to enroll in Medicare premium Part A or Part B using the new SEPs. We believe our proposals will create the flexibility needed for eligible individuals to enroll in the program while simultaneously establishing parameters to ensure appropriate use of the new exceptional conditions SEPs.

In determining what new exceptional conditions SEPs would be beneficial to the Medicare program and its beneficiaries and that should be established in regulations, CMS considered numerous factors including the following:

- Whether the conditions that caused the individual to miss an enrollment period are “exceptional” as required under the CAA, and whether they are likely to be a one-time event.
- The SEP should not create an incentive for individuals to delay timely enrollment into Medicare.
- The SEP should not create an incentive for individuals to not educate themselves about the importance of enrolling in Medicare timely and make informed decisions during other available enrollment periods.
- Whether an SEP would be the most appropriate resolution to the exceptional conditions in question and whether other remedies such as individualized equitable relief under section 1837(h) of the Act, would more appropriately apply.
- The SEP should be expected to apply to a significant number or broad category of individuals, which would justify the establishment of a specific SEP in regulation instead of relying on the Secretary’s authority under section 1837(h) of the Act to evaluate individual conditions and approve SEPs on a case-by-case basis.

With these parameters in mind, we leveraged our previous program experience with Medicare enrollment in determining which SEPs to propose. We also considered the SEPs for exceptional conditions established under Medicare Parts C and D (section 1851(e)(4) of the Act), the Health Insurance Marketplace (29 U.S.C. 1163), and commercial health plans for insight into what SEPs are available in both public and private healthcare settings. Finally, we also considered whether the proposed new SEPs and the associated entitlement would protect access

to continuous coverage for individuals eligible for Medicare Part A and Part B, such as through expediting individuals' entitlement date or by creating opportunities for individuals to enroll in coverage sooner.

Based on these considerations, CMS is proposing to establish five SEPs under Medicare Parts A and B based on the Secretary's authority in section 1837(m) of the Act. Four of the proposed SEPs address specific exceptional conditions. One SEP would permit CMS or SSA to evaluate individuals' particular conditions and grant SEPs on a case-by-case basis due to unanticipated conditions that may arise in the future. We anticipate these proposed changes would have a positive impact on Medicare beneficiaries, including those in communities impacted by lack of continuous health coverage.

To accommodate these changes, we propose to establish a new § 406.27, entitled "Special enrollment periods for exceptional conditions" to provide SEPs for individuals who missed enrolling in premium Part A during an enrollment period due to exceptional conditions. Similarly, we propose to establish a new § 407.23, also entitled "Special enrollment periods for exceptional conditions" to provide SEPs for individuals who missed enrolling in Part B during an enrollment period due to exceptional conditions. Both proposed §§ 406.27(a) and 407.23(a) would provide in part that the SEPs for exceptional conditions would be available beginning January 1, 2023. Specifically, the proposed SEPs for exceptional conditions would be applicable for exceptional conditions that took place on or after January 1, 2023 with the exception of the SEP to Coordinate with Termination of Medicaid Coverage discussed in section II.2.d. of this proposed rule.

Each of these SEPs would provide an opportunity for individuals to enroll without having to wait for the GEP. Individuals who enroll in Medicare Part A or Part B using an SEP for

exceptional conditions and subsequently disenroll would have to wait until the next GEP or another SEP to reenroll and may potentially be subjected to a LEP.

Late Enrollment Penalties Associated with Special Enrollment Periods for Exceptional Conditions

Section 120(a)(2)(C)(ii) of the CAA modified section 1839(b) of the Act to provide that individuals who enroll during an SEP established under the Secretary's authority under new section 1837(m) of the Act are not subject to the LEP. Specifically, section 1839(b) of the Act, as amended, provides that an individual who enrolls in Medicare "after his initial enrollment period [...] and not pursuant to a special enrollment period under subsection (i)(4), (l), or (m) of section 1837 [...] shall be increased by 10 percent of the monthly premium so determined for each full 12 months (in the same continuous period of eligibility) in which he could have been but was not enrolled." Therefore, we propose that should an individual who missed an enrollment period due to an exceptional condition, enroll in premium Part A or Part B using one of the following SEPs, they would not be subject to a LEP. Specifically, we are proposing at § 406.33(c)(2) that for enrollments on or after January 1, 2023 under one of the SEPs established pursuant to the Secretary's authority in section 1837(m) of the Act and established in § 406.27, any months of non-coverage would be excluded from the calculation of the LEP. Similarly, we are proposing at § 408.24(b)(2) that for enrollments on or after January 1, 2023 under one of the SEPs established pursuant to the Secretary's authority in section 1837(m) of the Act and established in § 407.23, any months of non-coverage would be excluded from the calculation of the LEP.

We are also proposing changes to our regulations to reflect that certain individuals who reenroll in premium Part A or Part B would also be exempted from paying an LEP. Specifically,

we are proposing under §§ 406.34(a) and 408.24(c) that, for individuals who reenroll prior to January 1, 2023, the requirements currently in place for determining the months taken into account for purposes of calculating the LEP would continue to apply. In addition, we are proposing in §§ 406.34(e) and 408.24(d)(2)(ii) that for reenrollments on or after January 1, 2023, pursuant to one of the SEPs for exceptional conditions established under the Secretary's authority in section 1837(m) of the Act and promulgated in §§ 406.27 or 407.23, respectively, any months of non-coverage would be excluded from the calculation of the LEP. However, if the individual fails to enroll or reenroll during the available exceptional condition SEP, any months of non-coverage, including the months during the exceptional condition SEP, would be taken into consideration for calculating the LEP in accordance with §§ 406.33, 406.34, and 408.22.

In the following sections, we discuss each of the proposed SEPs for exceptional conditions.

a. SEP for Individuals Impacted by an Emergency or Disaster

The severity and duration of extreme weather-related events and other emergencies can be difficult to accurately predict, but may strip individuals of their ability to carry out day-to-day activities. In many cases, impacted individuals need additional time after the end of an emergency to return to their normal routine. We know from program experience that these events can result in disruptions in mail delivery, SSA office closings, and operational delays at Social Security field offices, any of which can prevent individuals from submitting their enrollment applications in a timely manner.

For Medicare Parts A and B, we have the authority under section 1837(h) of the Act to provide relief to individuals whose enrollment or non-enrollment in Part A or Part B was

unintentional or erroneous and resulted from an error, misrepresentation or inaction by the federal government. Disrupted mail delivery and Social Security office closures due to disasters might justify relief under 1837(h) in some cases. For example, during the COVID-19 pandemic, we utilized this equitable relief authority to provide assistance to individuals who missed their opportunity to enroll in Medicare during their IEP, GEP, or SEP. However, disasters or emergencies may interfere with individuals' ability to enroll in Medicare without any error or inaction by the Federal government. As a result, these conditions would not meet the requirements for equitable relief under section 1837(h) of the Act.

To address such exceptional conditions, we are proposing an SEP for individuals impacted by an emergency or disaster under the Secretary's authority to establish SEPs beginning January 1, 2023, under section 1837(m) of the Act. Establishing such an SEP would permit the agency to provide immediate relief to individuals impacted by certain emergencies and disasters without being subject to the requirements applicable under our existing equitable relief authority. Providing an SEP for individuals who missed enrolling in Medicare during an enrollment period because they were impacted by an emergency or disaster will permit Medicare beneficiaries to maintain healthcare coverage and access healthcare services in times of disruption when healthcare may be most critical. We believe these effects would be most significant, and the proposed SEP for individuals impacted by an emergency or disaster would be most beneficial, for communities where social risk factors such as food, housing, or financial insecurity are prevalent.

CMS is proposing, at new §§ 406.27(b) and 407.23(b), to create an SEP for individuals prevented from submitting a timely Medicare enrollment request by an emergency or disaster declared by either a Federal, state, or local government. These SEPs would apply for individuals

enrolling in premium Part A or Part B and would eliminate potential gaps in coverage and otherwise applicable LEPs resulting from eligible individuals' inability to submit a timely enrollment request as a result of emergency or disaster.

At new §§ 406.27(b)(1) and 407.23(b)(1), we propose this SEP would be available to those who were not able to enroll in premium Part A or Part B or both if they reside (or resided) in an area for which a Federal, state or local government entity newly declared a disaster or other emergency. The individual must demonstrate that they reside (or resided) in the area during the period covered by that declaration. We understand that not every emergency declaration would impact an individual's ability to enroll in a timely manner. Therefore, we are specifically soliciting comments regarding this proposal, including whether CMS should limit the time frame of the SEP based on the type of emergency, or specify that the type of emergency must explicitly restrict an individual's ability to enroll.

At §§ 406.27(b)(2) and 407.23(b)(2), we propose that the SEP would begin on the date an emergency or disaster is declared, or if different, the start date identified in the declaration, whichever is earlier, so long as the date is on or after January 1, 2023. The SEP ends 2 months after the end date identified in the disaster or emergency declaration or, if applicable, the end date of any extensions or the date when the declaration has been determined to have ended or has been revoked. The intention of having the SEP end 2 months after the end of the declaration is to provide individuals enough time to recover from the emergency before needing to enroll in Medicare.

We are proposing in §§ 406.27(b)(3) and 407.23(b)(3), according to the Secretary's authority under section 1838(g) of the Act to specify the coverage period for individuals enrolling during SEPs established under section 1837(m) of the Act, that the coverage period for

individuals who enroll under this SEP would begin the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

b. SEP for Health Plan or Employer Misrepresentation or Providing Incorrect Information

As codified in § 406.6(c) of our regulations, some individuals are not auto-enrolled into Medicare, and thus must apply in order to enroll. Often, the primary source of information about Medicare for working aged individuals is their employer or the carrier of their GHP. CMS is aware of multiple instances in which individuals received erroneous information from their employer that resulted in the individual not enrolling in Part B timely and consequently they were assessed an LEP. CMS's ability to offer assistance to individuals who are misinformed about Medicare enrollment periods by their employer or GHP is very limited. As a result, these individuals have historically faced gaps in coverage or been required to pay significant LEPs for the rest of their lives after failing to enroll in Part B based on misrepresentation by an employer, GHP or a representative of such an entity.

In order to provide relief to individuals who missed an enrollment period because of misrepresentation by or incorrect information from their employer or GHP, we are proposing to create a new SEP at § 406.27(c) and at § 407.23(c) based on exceptional conditions. This SEP would apply for individuals whose non-enrollment in premium Part A or Part B is unintentional, inadvertent, or erroneous and results from material misrepresentation or reliance on incorrect information provided by the individual's employer or GHP, or any person authorized to act on behalf of the employer or GHP. We are proposing at §§ 406.27(c)(1) and 407.23(c)(1) that an individual is eligible for such an SEP if they can demonstrate that he or she did not enroll in premium Part A or Part B during an enrollment period in which they were eligible based on information received from an employer or GHP, or any person authorized to act on such

organization's behalf, and an employer, GHP or their representative materially misrepresented information or provided incorrect information relating to enrollment in premium Part A or Part B, so long as the misrepresentation or error occurred on or after January 1, 2023.

To demonstrate material misrepresentation, an individual would be required to provide documentation of the relevant misrepresentation to SSA. The documentation must show that the information was provided on or after January 1, 2023, was directly from an employer, GHP or their representative prior to an enrollment period, and that the inaccuracy caused the individual not to enroll timely. Examples of such evidence could be a letter from the employer or GHP that materially misrepresents the Medicare enrollment process or a letter from the employer or GHP acknowledging that they provided misinformation in a previous communication. An omission by the employer or GHP or the representative of such organization would not be considered a misrepresentation for purposes of this proposed SEP, as employers and GHPs do not have an affirmative responsibility to educate employees about Medicare.

We are proposing at § 406.27(c)(2) and § 407.23(c)(2) that this SEP would begin the day the individual notifies SSA of the employer or GHP misrepresentation or incorrect information provided, so long as the misrepresentation or error occurred on or after January 1, 2023, and would end 2 months later. Individuals would be required to provide SSA or CMS evidence that shows what misinformation was initially provided by the employer, GHP, or their representative. We are soliciting comments on whether we should require additional evidence, for example, evidence of what new information was received that caused discovery of the misinformation and evidence of when the discovery was made. Finally, at §§ 406.27(c)(3) and 407.23(c)(3), we propose that the coverage period would begin the first day of the month following enrollment.

c. SEP for Formerly Incarcerated Individuals

Section 1862(a)(2) and (3) of the Act generally prohibits Medicare payment for covered services while the recipient is incarcerated, as the incarcerated individual is provided healthcare through their penal institution. Further, section 202(x)(1)(A) of the Act prohibits the payment of Old-age, Survivors, and Disability Insurance (OASDI) benefits to individuals who are incarcerated. Therefore, if an individual turns 65 and qualifies for Medicare while incarcerated (meaning the individual is in custody of penal authorities as described in 42 CFR 411.4(b)) and is not yet receiving OASDI benefits, that individual is not automatically enrolled in Medicare Part A. Moreover, current law does not provide any special enrollment opportunities for formerly incarcerated individuals who miss a Medicare enrollment period while incarcerated. If these individuals do not enroll into Medicare because they are incarcerated, they may go months without health coverage upon their release. For example, upon their release such individuals would only be able to enroll in Medicare during the GEP which could result in a significant delay in coverage. Further, delaying enrollment means that they may incur an LEP for premium Part A and/or Part B for the rest of their lives. Regardless of whether they are newly eligible for Medicare coverage or not, individuals who are incarcerated are required to begin and maintain their monthly premium payments for premium Part A and/or Part B to avoid termination of Medicare coverage.

To address the exceptional conditions that an individual faces while incarcerated as described previously, and to ensure that formerly incarcerated individuals have access to health coverage under Medicare, we are proposing at §§ 406.27(d) and 407.23(d) an SEP for individuals who are released from incarceration on or after January 1, 2023. This SEP would allow formerly incarcerated individuals to avoid potential gaps in coverage and late enrollment

penalties. We propose at §§ 406.27(d)(1) and 407.23(d)(1) that an individual would be eligible for this SEP if they demonstrate that they are eligible for Medicare and failed to enroll or reenroll in Medicare premium Part A or Part B during another enrollment period in which they were eligible to enroll while they were incarcerated. Further, there must be a record of release either through discharge documents or data available to SSA.

We propose at §§ 406.27(d)(2) and 407.23(d)(2) that this SEP would start the day of the individual's release from incarceration and end the last day of the sixth month after the month in which the individual is released from incarceration. We propose this duration because (1) it takes approximately 3 months for OASDI payments to be reinstated upon an individual's release from incarceration; and (2) data demonstrate that individuals with arrest or conviction records face barriers in obtaining employment. Such lack of income from employment or OASDI might dissuade formerly incarcerated individuals from enrolling in Medicare upon their release because of concerns about their ability to pay Medicare premiums and cost sharing. Formerly incarcerated individuals may experience social risk factors including financial, housing or food insecurity, social isolation, and other factors that can increase the likelihood of chronic physical or mental health conditions that require healthcare services. Lack of institutional support may impair the ability of formerly incarcerated persons from obtaining employment, housing, and other stabilizing supports necessary for successful reentry. Therefore, by providing this extended SEP duration, we ensure this at-risk population has adequate opportunity to enroll in Medicare. Further, we anticipate this change having a positive impact on formerly incarcerated Medicare beneficiaries, including those in communities who may be disproportionately impacted by a lack of continuous health coverage.

Finally, at new §§ 406.27(d)(3) and 407.23(d)(3), we propose that entitlement would begin the first day of the month after the month of enrollment, so long as it is after January 1, 2023.

d. SEP to Coordinate with Termination of Medicaid Coverage

Many beneficiaries are enrolled in Medicaid when they initially qualify for Medicare at age 65, or if they are under age 65, after receiving 24 months of Social Security Disability Insurance (SSDI). While some of these individuals retain Medicaid coverage after becoming eligible for Medicare, others lose Medicaid benefits or eligibility entirely. For example, when an individual enrolled in the adult group under § 435.119 becomes eligible for Medicare, they become ineligible for the Medicaid adult group. (Individuals enrolled in the adult group have an annual income below 138 percent of the Federal Poverty Level (\$20,398 for an individual in 2022)).³ Unless such individuals are eligible for Medicaid on another basis, they will no longer be eligible for Medicaid. Many such individuals qualify for another Medicaid eligibility group, such as a Medicare Savings Programs (MSP) group, but others lose Medicaid coverage entirely because they do not qualify for another Medicaid eligibility group.

Low-income Medicare beneficiaries experience poorer health outcomes than their higher-income counterparts.⁴ Based on program experience and reports from stakeholders, we are aware that some individuals who lose all Medicaid coverage after newly qualifying for Medicare may experience confusion and administrative barriers that undermine a seamless transition from

³ The adult group under § 435.119 (b) has an income limit of 133 percent of the FPL, but a basic standard deduction of 5 percent of the FPL is applicable as described in section 6012(a)(1) of the Internal Revenue Services Code. (See 42 CFR 434.603(e).)

⁴ For information about the health outcomes of low-income Medicare beneficiaries, see HHS Office of the Assistant Secretary for Planning and Evaluation (2016, December). *Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs*.
https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf

Medicaid to Medicare coverage, risking a period of time without health insurance and a possible LEP for these at-risk individuals.

Before terminating or reducing the scope of Medicaid coverage for individuals who become eligible for Medicare, the state Medicaid agency must conduct a redetermination of eligibility, including a determination of whether the individual is eligible for Medicaid upon another basis (42 CFR 435.916(d) and 435.916(f)(1)). The state must continue the same level of Medicaid coverage until the state completes the eligibility redetermination and provides at least 10 days advance notice and fair hearing rights in accordance with § 435.917 and 42 CFR part 431 Subpart E. If during the redetermination process, an individual is found to no longer be eligible for the eligibility group under which they had been most recently receiving coverage, the state would then: (1) move the individual to a different eligibility group, which could include an MSP eligibility group, for which the person is eligible; or (2) determine the individual's potential eligibility for other insurance affordability programs, in accordance with § 435.916(f)(2), and terminate the individual's Medicaid coverage.

Despite these requirements, there are multiple scenarios that can prevent a seamless transition to Medicare coverage. States sometimes fail to complete redeterminations timely. Additionally, individuals sometimes lose coverage for procedural reasons (for example, failure to submit required paperwork in time) even though they likely remain eligible for Medicaid.⁵ In the first situation, while § 435.916(d) requires that states “promptly” conduct redeterminations based on changes in circumstances, including new eligibility for Medicare, we believe that some states do not complete redeterminations until months after the individual first becomes eligible for

⁵ See HHS Office of the Assistant Secretary for Planning and Evaluation. (2019, May 8). *Loss of Medicare-Medicaid Dual Eligible Status: Frequency, Contributing Factors and Implications*. <https://aspe.hhs.gov/reports/loss-medicare-medicicaid-dual-eligible-status-frequency-contributing-factors-implications>, page 38.

Medicare even though Medicare eligibility is generally predictable.⁶ If a state does not complete a redetermination when the beneficiary attains Medicare eligibility, an individual may retain Medicaid even though the individual no longer technically meets the Medicaid eligibility criteria. State Health Insurance Assistance Programs and beneficiary advocacy groups report that these individuals may then miss their IEP because they continue to be covered by Medicaid and may think they do not need or cannot afford Medicare coverage at that time, especially when individuals expect to be liable for Medicare premiums. While some states cover the Part B premiums for individuals remaining in the adult group pending a redetermination under their buy-in agreement,⁷ others do not.⁸ States cannot include the payment of the Part A premium for

⁶ Recent HHS Office of Inspector General reports and state audits have cited cases in which states continued to provide coverage for many months after a change impacting eligibility was identified that should have prompted a redetermination. See for example:

Louisiana Legislative Auditor. (2018, November 8). *Medicaid Eligibility: Wage Verification Process of the Expansion Population*.

[https://www.lla.la.gov/PublicReports.nsf/1CDD30D9C8286082862583400065E5F6/\\$FILE/0001ABC3.pdf](https://www.lla.la.gov/PublicReports.nsf/1CDD30D9C8286082862583400065E5F6/$FILE/0001ABC3.pdf);

HHS Office of the Inspector General. (2019a, August). *Colorado Did Not Correctly Determine Medicaid Eligibility for Some Newly Enrolled Beneficiaries*. <https://oig.hhs.gov/oas/reports/region7/71604228.pdf>;

HHS Office of the Inspector General. (2019b, August). *Illinois Medicaid Managed Care Organizations Received Capitation Payments After Beneficiaries' Deaths*. <https://oig.hhs.gov/oas/reports/region5/51800026.pdf>;

HHS Office of the Inspector General. (2019c, May). *California Medicaid Managed Care Organizations Received Capitation Payments After Beneficiaries' Deaths*. <https://oig.hhs.gov/oas/reports/region4/41806220.pdf>;

HHS Office of the Inspector General. (2018d, October). *Ohio Medicaid Managed Care Organizations Received Capitation Payments After Beneficiaries' Deaths*. <https://oig.hhs.gov/oas/reports/region5/51700008.pdf>.

⁷ Under their buy-in agreements with CMS, some states are required to enroll all Medicaid beneficiaries in Medicare Part B and to pay the premiums on their behalf (known as “Part B buy-in”). If such a state has not completed the eligibility redetermination for an individual enrolled in the adult group before the first month they qualify for Medicare, the state must enroll the individual in Part B buy-in for all months in which the individual is enrolled in the adult group. CMS Manual for the State Payment of Medicare Premiums, chapter 1, section 1.4, <https://www.cms.gov/files/document/chapter-1-program-overview-and-policy.pdf>.

⁸ See section II.D.3.e. of this proposed rule for a discussion of buy-in coverage groups available for Part B.

adult group beneficiaries in their buy-in agreement.⁹

During the ongoing Public Health Emergency in response to the Coronavirus Disease 2019 outbreak (COVID-19 PHE), as a condition of receiving the federal medical assistance percentage (FMAP) increase authorized by the Families First Coronavirus Response Act (FFCRA) (P.L. 116-127), states have been required to maintain Medicaid enrollment for nearly all individuals enrolled in Medicaid as of March 18, 2020, through the end of the month in which the PHE ends. This condition, known as the continuous enrollment requirement, applies to, among others, individuals who qualified during this time period in the adult group and subsequently became eligible for Medicare. In the preamble to the interim final rule with comment period published in the November 6, 2020 **Federal Register** (85 FR 71142), CMS explained that states would be in compliance with the continuous enrollment requirement if they were to transition an adult group beneficiary who becomes eligible for Medicare to an MSP group for which such an individual is eligible (but that such an individual could not be transitioned to an MSP group if the individual did not meet the eligibility requirements for any MSP group). CMS articulated this policy after initially directing states that they had to retain such individuals in both the adult group and MSP groups in order to comply with the continuous enrollment requirement.¹⁰

Since the start of the COVID-19 PHE, beneficiary advocacy groups and State Health Insurance Assistance Programs have reported to us that a substantial number of beneficiaries who became eligible for Medicare while enrolled in the adult group may have interpreted states'

⁹ As described in section II.D.1. of this proposed rule, states can only pay the Part A premiums for individuals who enrolled in the Qualified Medicare Beneficiary (QMB) group.

¹⁰ See CMS. *COVID-19 Frequently Asked Questions (FAQs) for State Medicaid and Children's Health Insurance Program (CHIP) Agencies*. Last updated January 6, 2021, available at <https://www.medicaid.gov/state-resource-center/downloads/covid-19-faqs.pdf>

notifications that their Medicaid coverage would remain throughout the COVID-19 PHE (and the ensuing months of continuous coverage after they qualified for Medicare) to mean they did not need to take any action during the COVID-19 PHE to secure health coverage, including enrolling in Medicare. As mentioned previously, some beneficiaries who stay in the adult group are ineligible for coverage of their Part B premiums under state buy-in. Further, certain beneficiaries should have been enrolled in Medicare on the basis of their state's buy-in agreement but were not because, although their state includes all Medicaid beneficiaries in their buy-in agreement for Part B premiums, the state may have been unclear this includes individuals whom states kept in the adult group on the basis of the continuous enrollment requirement. Consequently, some beneficiaries who maintained adult group eligibility are likely to have missed their IEPs as a result of confusion based on the COVID-19 PHE. Based on these reports, we are concerned that when the COVID-19 PHE ends and states resume routine eligibility and enrollment operations for Medicaid, including taking action on pending applications, renewals, and redeterminations necessitated by changes in beneficiary circumstances, such individuals may end up being terminated from Medicaid and will experience a gap in coverage and lose access to critical health care as a result. Further, once they do enroll in Medicare, they may incur late enrollment penalties.

As an existing requirement under the Medicaid program designed to maximize continuity of coverage for beneficiaries whom states have determined ineligible for Medicaid, states must determine or assess their potential eligibility for other Insurance Affordability Programs, such as the Children's Health Insurance Program (CHIP) and health insurance coverage available on the Marketplace with financial assistance and transfer their accounts to such programs as appropriate under §§ 435.916(f)(2) and 435.1200(e). Although Insurance Affordability Programs have not

been defined to include Medicare, we believe promoting a seamless transition from Medicaid to Medicare coverage is also very important. The ability to enroll in Medicare can be vital in preventing gaps in health coverage, especially if individuals lack access to other health insurance and may be subject to an LEP when they do enroll in Medicare.

To remove barriers that present an exceptional condition that could prevent individuals from transitioning from coverage under the Medicaid program to coverage under the Medicare program, we are proposing an SEP at §§ 406.27(e) and 407.23(e) for individuals who lose Medicaid eligibility entirely after the COVID-19 PHE ends or on or after January 1, 2023 (whichever is earlier) and have missed a Medicare enrollment period. We anticipate our proposals will advance health equity by improving low-income individuals' access to continuous, affordable health coverage and use of needed health care consistent with the *Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* and the *Executive Order on Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage*.

We are proposing at §§ 406.27(e)(1) and 407.23(e)(1) that to be eligible for this SEP, an individual must demonstrate they are eligible for Medicare and their Medicaid eligibility is terminated on or after January 1, 2023, or is terminated after the last day of the COVID-19 PHE as determined by the Secretary, whichever is earlier. At §§ 406.27(e)(2)(i) and 407.23(e)(2)(i), we propose that if the termination of Medicaid eligibility occurs after the last day of the COVID-19 PHE and before January 1, 2023, the SEP starts on January 1, 2023 and ends on June 30, 2023. At §§ 406.27(e)(2)(ii) and 407.23(e)(2)(ii), we propose that if the termination of Medicaid eligibility occurs on or after January 1, 2023, the SEP starts when the beneficiary receives notice of an upcoming termination of Medicaid eligibility and ends 6 months after the termination of

eligibility. We believe this extended duration would allow this at-risk population sufficient opportunity to enroll in Medicare.

We note that unlike the other proposed SEPs for exceptional conditions, this SEP could apply to a circumstance that occurs before January 1, 2023 (that is, if the end of the PHE and the individual's Medicaid termination occur before such time). We believe that such a deviation is warranted in this limited circumstance given the novel COVID-19 outbreak and unprecedented federal, state and local efforts to combat it. As mentioned earlier, to comply with the continuous enrollment requirement under section 6008 of FFRCA, states have kept substantial numbers of beneficiaries in the adult group for several months after they qualified for Medicare (more than 2 years in some cases). As described previously, state notices regarding extended Medicaid eligibility and the provision of continuous enrollment may have contributed to confusion, causing many individuals to miss their IEP during the PHE. To minimize beneficiary burden and help reduce gaps in coverage from Medicaid-only to Medicare-only once states restore routine eligibility and enrollment operations, it is critical to provide this SEP to individuals who lose coverage after the PHE if that occurs before January 1, 2023. In short, the PHE presents a unique convergence of circumstances that will affect a defined group of individuals currently known to CMS.

We propose at §§ 406.27(e)(3) and 407.23(e)(3) that entitlement would begin the first day of the month following the month of enrollment, so long as it is effective after the end of the PHE or January 1, 2023, whichever is earlier. We note that individuals whose Medicaid eligibility is terminated after the end of the COVID-19 PHE, but before January 1, 2023 (if applicable), have the option of requesting that entitlement begin back to the first of the month following termination of Medicaid eligibility provided the individual pays the monthly premiums

for the period of coverage.

Lastly, we propose at §§ 406.27(e)(4) and §407.23(e)(4) that individuals who otherwise would be eligible for this SEP, but enrolled during the COVID-19 PHE prior to January 1, 2023, if applicable, are eligible to have LEPs collected under §§ 406.32(d) or 408.22 reimbursed and ongoing penalties removed. Given the unique nature of this specific SEP, and the fact that we are proposing that individuals could be eligible for the SEP if the COVID-19 PHE ends before January 1, 2023, we believe it is appropriate and fair that these individuals not be subject to an LEP that would not have been collected had they known about this remedy at the time of enrollment.

This proposed SEP would allow an individual who loses Medicaid eligibility entirely once the PHE ends or on or after January 1, 2023, if earlier, and who has missed a Medicare enrollment period, to enroll in Medicare without a gap in coverage or an LEP. We anticipate that the SEP would most frequently apply to individuals who do not sign up for Medicare while they still have Medicaid, including those eligible in the adult group. At least initially, we suspect that the individuals who are most likely to need and use this proposed SEP are those who were in the Medicaid adult group under § 435.119, especially those individuals who remained in the adult group during the COVID-19 PHE and while pending an eligibility determination once normal operations resume because, for example, they believe they do not need additional coverage or cannot afford to pay the Medicare premiums. This SEP would apply to individuals who lose Medicaid coverage altogether, regardless of whether the Medicaid termination results from their new eligibility for Medicare, other changes in circumstances, or procedural reasons. As noted previously, an individual would need to have missed a Medicare enrollment period and if eligible, the SEP would be available once the individual is notified of their Medicaid termination.

Further, individuals who are determined to no longer meet the eligibility requirements for one Medicaid eligibility group but are determined eligible for a separate Medicaid eligibility group that is included in their state's buy-in agreement would not use this SEP because they do not need it as the state can already enroll them in Medicare without regard to Medicare enrollment periods and LEPs.

We seek comment on the parameters of this proposed SEP, particularly whether the SEP's duration (that is, the trigger, which is after the loss of Medicaid eligibility, rather than while the individual is still enrolled in Medicaid, as well as the end date for the SEP) and Medicare entitlement date (that is, earliest date Medicare benefits can start) prevent gaps in coverage and promote continuity of care for low-income beneficiaries who lose Medicaid coverage after qualifying for Medicare.

e. SEP for Other Exceptional Conditions

CMS is proposing to retain the ability to provide SEPs on a case-by-case basis for other unanticipated situations that involve exceptional conditions and warrant an SEP. This SEP would allow us to grant SEPs on a case-by-case basis for circumstances we do not have enough experience to consider or anticipate that could create a barrier to enrollment. We acknowledge that there is no way to predict the full range of circumstances that would warrant an SEP – they are “exceptional” – so we need this SEP for exceptional conditions to be timely in our response to beneficiaries with unique cases, given the time it takes to establish a more targeted SEP via rulemaking. There is a similar SEP under Medicare Part C and Part D, and we are leveraging our experience from those programs to afford beneficiaries who have unique exceptional conditions beyond their control that prevent them from enrolling in Medicare, an SEP. In addition, some of the SEPs that are now codified under Part C and Part D started out as case-by-case SEPs. We

were able to use the information and experience gained as a basis for establishing a new SEP, through rulemaking, for a broad category of people corresponding to a more specific set of circumstances.

Specifically, we are proposing to create an SEP for other exceptional conditions to provide individuals an opportunity to enroll in premium Part A, Part B or both. This SEP would provide an enrollment opportunity for individuals where conditions beyond their control caused them to miss an enrollment period and prevented them from timely enrolling in premium Part A or Part B or both during the IEP, GEP or other prescribed SEPs. This SEP would apply to individuals whose unique conditions do not qualify for one of the other proposed SEPs and would be proposed at new §§ 406.27(f) and 407.23(f). We are proposing at §§ 406.27(f)(1) and 407.23(f)(1) that such SEPs would be granted on or after January 1, 2023, if two conditions are met. First, an individual must demonstrate that conditions outside of their control caused them to miss an enrollment period. Second, the condition must be determined exceptional in nature.

Due to the numerous reasons an individual might request an SEP for other exceptional conditions, individuals may reasonably need different amounts of time to enroll in Medicare in the event an SEP is granted. Setting forth a specific duration for this SEP could disadvantage enrollees whose condition may require additional time. In light of these facts, at §§ 406.27(f)(2) and 407.23(f)(2), we propose that the SEP duration would be determined on a case-by-case basis. CMS believes that this SEP will be infrequently used and that it will only be granted in conditions that are truly exceptional in nature. This SEP will not be used to grant individuals enrollment due to forgetfulness or lack of knowledge. For example, an individual who turns 65 and fails to enroll because they simply forgot to enroll during their IEP would not qualify for this proposed SEP as they do not have evidence that their situation that prevented them from

enrolling timely was beyond their control nor was it exceptional in nature. Finally, consistent with the other SEPs we are proposing under section 1837(m) of the Act at §§ 406.27(f)(3) and 407.23(f)(3) that entitlement would begin the first day of the month following the month of enrollment, and only for exceptional conditions that arise on or after January 1, 2023.

f. Alternatives Considered

As discussed previously, we considered several factors in determining which SEPs to propose under the new authority established by section 120 of the CAA. With these principles in mind, and to provide relief for individuals in truly exceptional conditions as directed by section 120 of the CAA, there were a number of SEPs that we considered but did not believe warranted establishing a separate SEP for exceptional conditions. For example, we considered an SEP for individuals who previously decided not to enroll in Medicare but now want to enroll outside of the GEP or other enrollment periods because they are experiencing a health event and want Medicare coverage. We decided not to propose an SEP for individuals in such conditions because there was not an exceptional condition that prevented the individual from enrolling during an earlier enrollment period; allowing enrollment outside of the GEP could provide an incentive for other individuals to delay enrollment in Medicare, which we believe is inconsistent with the statutory framework that imposes penalties for late enrollment. We also considered an SEP for individuals who lost Medicare coverage due to non-payment of premiums who are not eligible for another SEP or equitable relief and now want to re-enroll outside of the GEP. We opted not to propose this SEP because we did not want to create an environment where there could be cycles of an individual losing and reenrolling in Medicare based on whether they have paid their premiums. If a beneficiary is experiencing financial constraints, there are mechanisms in place (including state buy-in, MSP and premium payment plans) that would more

appropriately provide support for affected individuals while ensuring continuity in their health care coverage.

In order to be eligible for any of the SEPs other than the new exceptional condition SEPs, individuals must have had separate health insurance coverage when they first become eligible for Medicare and have elected not to enroll (or to be deemed enrolled) during their IEP. To be consistent with the existing Medicare SEPs and to ensure appropriate use of the exceptional condition SEPs, we considered proposing a requirement that new SEPs would only be available to individuals who have missed their IEP due to an exceptional condition. However, because of the potential need to use the exceptional condition SEPs outside of the IEP and because section 1837(m) of the Act allows for additional flexibility to establish these SEPs we have not included this limitation.

We welcome comments on our proposed changes to the coverage period dates and on our proposed SEPs for exceptional conditions. We note that we may establish additional SEPs for exceptional conditions through rulemaking in the future if experience demonstrates that additional SEPs would be necessary or beneficial. We also welcome recommendations for additional SEPs based on exceptional conditions. We request that any suggestions for additional SEPs for exceptional conditions include a robust discussion of why commenters believe the potential SEPs would be consistent with the policy considerations and guiding parameters discussed previously.

3. Technical Correction to the Calculation of the Late Enrollment Penalty for Individuals Enrolling on or After January 1, 2023.

Currently, section 1839(b) of the Act specifies that the LEP is based on the number of months that have elapsed between the close of the individual's IEP and the close of the

enrollment period during which they enroll, plus certain additional months for individuals who reenroll. However, section 120(a)(3) of the CAA amended section 1839(b) of the Act to specify that, for enrollments on or after January 1, 2023, the months that will be taken into account for purposes of determining any LEP include months which elapse between the close of the individual's IEP and the close of the month in which they enroll, plus, for individuals who reenroll, the months that elapse between the date of termination of previous coverage and the close of the month in which the individual enrolls. We expect that these changes will decrease the number of months individuals are subject to the LEP. To implement these changes, we propose the following changes to our regulations:

- At § 406.33, we propose to revise paragraph (a) to reflect the requirement that, for individuals enrolling for the first time, the existing Part A LEP calculation requirements continue to apply to enrollments before January 1, 2023.
- We also propose to redesignate paragraph (c) of § 406.33 as paragraph (d) and add new paragraph (c) to address the calculation of the LEP for individuals enrolling for the first time on or after January 1, 2023. Specifically, the introductory text of § 406.33(c) would require that the months to be counted for calculating the Part A LEP begin with the end of the individual's IEP, and extend through the end of the month in which the individual enrolls. In proposed § 406.33(c)(1), we would continue to exclude certain months from the calculation of the LEP, based on the requirements currently in effect under § 406.33(a)(1) through (6). We are proposing to exclude additional months from the calculation of the LEP for enrollments on or after January 1, 2023 at § 406.33(c)(2), however those changes are unrelated to the technical correction implemented under section 120(a)(3) of the CAA, and are discussed in greater detail in section II.A.2. of this proposed rule.

- At § 408.24, we propose to revise paragraph (a) to apply the existing Part B LEP calculation months and exceptions to individuals who satisfy the requirements of § 408.24 before January 1, 2023.

- At § 408.24, we also propose to redesignate paragraph (b) as paragraph (c) and add new paragraph (b) to address the calculation of the LEP for enrollments on or after January 1, 2023. Specifically, the paragraph at §408.24(b) would require that for individuals who satisfy the requirements of § 408.24 after January 1, 2023, the months to be counted for calculating the Part B LEP begin with the end of the individual's IEP, and extends through the end of the month in which the individual enrolls. In proposed § 408.24(b)(1), we would continue to exclude certain months from the calculation of the LEP, consistent with the requirements currently in effect under § 408.24 (a)(1) through (10). We are proposing to exclude additional months from the calculation of the LEP for enrollments on or after January 1, 2023 at § 408.24(b)(2), however those changes are unrelated to the technical correction implemented under section 120(a)(3) of the CAA, and are discussed in greater detail in section II.A.2. of this proposed rule.

- At § 406.34, we propose to revise paragraph (a) to reflect the requirement that, for individuals reenrolling in Premium Part A, the existing Part A LEP calculation requirements continue to apply to enrollments before January 1, 2023.

- At 406.34, we propose to redesignate paragraph (e) as paragraph (f) and add new paragraph (e) to address the calculation of the LEP for individuals reenrolling on or after January 1, 2023. Specifically, new § 406.34(e)(1) would require that the months to be counted for calculating the Part A LEP begin with the end of the individual's IEP and extend through the end of the month in which the individual reenrolls, and we would continue to include the months currently specified in paragraphs (b) and (d) of this section, as applicable, and the months from

the end of the first period of entitlement through the end of the month during the GEP in which the individual reenrolled. In proposed § 406.34(e)(2), we would exclude the months of non-coverage in accordance with an individual's use of an exceptional condition SEP under § 406.27. Those months are not counted for premium increases, provided the individual enrolls within the duration of the SEP.

- We are also proposing coordinating changes related to the LEP for reenrollments at § 408.24. Specifically, we propose to amend § 408.24, to revise newly redesignated paragraph (c) to apply the existing Part B LEP calculation months and exceptions for reenrollments to individuals who satisfy the requirements of § 408.24 before January 1, 2023. New § 408.24(d) would require that for individuals who satisfy the requirements of § 408.24 after January 1, 2023, the months to be counted for calculating the Part B LEP include the number of months elapsed between the close of the individual's IEP and the close of the month in which he or she first enrolled and the number of months elapsed between the individual's initial period of coverage and the close of the month in which he or she reenrolled (as well as the number of months elapsed between each subsequent period of coverage and the close of the month in which he or she reenrolled). In proposed § 408.24(d)(2)(i), we would continue to exclude certain months from the calculation of the LEP, consistent with the requirements currently in effect under § 408.24 (a)(1) through (10) and also excluding months before April 1981 during which the individual was precluded from reenrolling by the two-enrollment limitation in effect before that date. Further, as discussed previously, an individual who missed an enrollment period due to an exceptional condition, and who enrolls in Part B using an exceptional condition SEP, would not be subject to a LEP. Therefore, we propose in § 408.24(d)(2)(ii) that if an individual uses an exceptional condition SEP under § 407.23 any months of non-coverage would not be counted

towards the calculation of the SEP, provided the individual enrolls within the duration of the SEP.

B. Proposals for Extended Coverage of Immunosuppressive Drugs for Certain Kidney Transplant Patients (§§ 407.1, 407.55, 407.57, 407.59, 407.62, 408.20, and 423.30).

1. History and Definition of Benefit

In 1972, Congress enacted section 299I of the Social Security Amendments of 1972 (Pub. L. 92-603), which amended section 226 of the Act to allow qualified individuals with ESRD¹¹ under the age of 65, to enroll in the federal Medicare health care program, beginning in 1973. These requirements are now codified in section 226A of the Act and implemented in our regulations at 42 CFR 406.13. As mentioned earlier, section 226A(a) of the Act provides that certain individuals who are medically determined to have ESRD and apply for Medicare coverage are entitled to benefits under Medicare Part A and eligible to enroll in Part B. However, section 226A(b)(2) of the Act currently requires that an individual's entitlement under Part A and eligibility under Part B based on ESRD status ends with the 36th month after the month in which the individual receives a kidney transplant.

The termination of Medicare entitlement has led to some beneficiaries losing coverage of immunosuppressive drugs that transplant patients would still need. Per the 2018 US Renal Data System (USRDS) Annual Report, 32 percent of kidney transplant recipients ages 45–64 years old have no known or other creditable prescription drug coverage.¹² Section 402(a) of the CAA established an exception that permits certain beneficiaries who were successful kidney transplant

¹¹ Under 42 CFR 406.13(b), ESRD means that stage of kidney impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life.

¹² United States Renal Data System : *2018 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States*, Bethesda, MD, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2018, from <https://cjasn.asnjournals.org/content/14/3/327>

patients to receive a limited Part B benefit effective January 1, 2023 -- covering only those immunosuppressive drugs described in section 1861(s)(2)(J) of the Act. Section 402(b) of the CAA also amended section 1836(b) of the Act to support limited eligibility under Part B for beneficiaries whose entitlement to insurance benefits under Part A ends by reason of section 226A(b)(2). These individuals are eligible to enroll (or to be deemed enrolled) for the new Part B immunosuppressive drug benefit (herein referred to as the Part B-ID benefit).

Not all Medicare kidney transplant patients who lose entitlement to Part A coverage based on section 226A(b)(2), however, are eligible to enroll in the new Part B-ID benefit. The CAA provided that certain individuals are not eligible to enroll in the new program. In general, if the individuals are enrolled in certain specific forms of health insurance or other programs that cover immunosuppressive drugs, the individuals would not be eligible to enroll in the Part B-ID benefit. We will discuss the excepted individuals and the specific forms of insurance and programs in greater detail in section II.B.2.b of this proposed rule entitled “Determination of Eligibility” and in our proposed rule at § 407.55(b). Individuals that are seeking entitlement under the new Part B-ID benefit would also need to meet additional statutory criteria, as discussed in section II.B.2.b. of this proposed rule, and in the proposed rule at § 407.57. Individuals enrolled in the new Part B-ID benefit would not receive Medicare coverage for any other items or services, other than coverage of immunosuppressive drugs.

Section 402 of the CAA made conforming amendments to sections 1836, 1837, 1838, 1839, 1844, 1860D-1, 1902, and 1905 of the Act. We discuss each of those changes elsewhere in this document, along with the corresponding proposals to modify our regulations in order to implement these changes. We are proposing to revise §§ 407.1, 408.20, 410.30, 423.30 and establish a new Subpart D (§§ 407.55 through 407.65) in 42 CFR part 407, entitled *Part B*

Immunosuppressive Drug Benefit to implement the new Part B-ID benefit.

Sections 226A, 1836(b) and 1837(n) of the Act provide the statutory authority for this new, limited Medicare entitlement program, and we are proposing to add a description of this basis for the Part B-ID benefit at § 407.1(a)(6). We specifically propose in § 407.1(a)(6) that, sections 1836(b) and 1837(n) of the Act will provide for coverage of immunosuppressive drugs as described in section 1861(s)(2)(J) of the Act under Part B beginning on or after January 1, 2023. Coverage of immunosuppressive drugs would be for eligible individuals whose benefits under Medicare Part A and eligibility to enroll in Part B on the basis of ESRD would otherwise end with the 36th month after the month in which the individual receives a kidney transplant by reason of section 226A(b)(2) of the Act.

We are also proposing to revise § 407.1(b) and establish a new paragraph (2) to incorporate the eligibility, enrollment, and entitlement requirements for the Part B-ID benefit within the scope of part 407. We specifically propose to revise § 407.1(b) to retain the language that states that part 407 sets forth the eligibility, enrollment, and entitlement requirements and procedures for supplementary medical insurance at § 407.1(b)(1), including the reference to the rules governing premiums in part 408 of this chapter. At new § 407.1(b)(2), we propose to add language stating that this part also sets forth the eligibility, enrollment, and entitlement requirements and procedures for the immunosuppressive drug benefit provided for under sections 1836(b) and 1837(n) of the Act, including the short title for the Part B-immunosuppressive drug benefit (Part B-ID).

The Part B-ID benefit is unique because it is available to a defined subset of Medicare beneficiaries and provides coverage only for immunosuppressive drugs. Since immunosuppressive drug therapy is a Part B benefit under section 1861(s)(2)(J) of the Act,

certain rules and requirements applicable to Part B apply to the Part B-ID benefit. Where there are specific differences, we address them in this rulemaking.

2. Part B-ID Benefit Eligibility, Enrollment, Entitlement, and Termination

a. Eligibility for the Part B-ID Benefit

Section 402(a)(2) of the CAA adds section 1836(b) of the Act, which establishes specific eligibility criteria for the Part B-ID benefit. Subject to exceptions, new section 1836(b)(1) of the Act provides that individuals whose entitlement to insurance benefits under Part A ends (whether before, on, or after January 1, 2023) by reason of section 226A(b)(2), and who meet certain additional requirements, would be eligible to enroll (or to be deemed enrolled) in Part B solely for purposes of coverage of immunosuppressive drugs in accordance with section 1837(n) of the Act. The principal limitations on eligibility for the Part B-ID benefit are set out in new section 1836(b)(2) of the Act. Under section 1836(b)(2)(A) of the Act, individuals enrolled in certain other types of health coverage would not be eligible for the Part B-ID benefit. As discussed in greater detail in this section, we are proposing to specify that an individual who has such other health coverage would not be eligible for the Part B-ID benefit in § 407.55(b).

b. Determination of Eligibility

Section 1836(b)(2)(B)(i) of the Act requires the Secretary, in coordination with the Commissioner of Social Security (Commissioner), to establish a process for determining whether an individual who is to be enrolled, or deemed to be enrolled, in the Part B-ID benefit meets the requirements for such enrollment, including the requirement that the individual not be enrolled in other health coverage that would make them ineligible for the Part B-ID benefit under 1836(b)(2)(A) of the Act.

In order for an individual to be enrolled in the Part B-ID benefit, section

1836(b)(2)(B)(ii)(I) of the Act requires that an individual provide to the Commissioner an attestation that they are not enrolled and do not expect to enroll in the excepted coverage, as described in section II.B.2.a. of this proposed rule (“Eligibility for the Part B-ID Benefit”), that would make the individual ineligible for the Part B-ID benefit under section 1836(b)(2)(A) of the Act. Section 1836(b)(2)(B)(ii)(II) of the Act requires that the individual notify SSA within 60 days of enrollment in such excepted coverage. Based on these requirements, we are proposing at § 407.59(a) and (b), that all prospective enrollees in the Part B-ID benefit must provide to the Commissioner, in the form and manner specified by CMS and SSA in the final rule, an attestation that the individual is not enrolled and does not expect to enroll in other health coverage that would make the individual ineligible for the Part B-ID benefit, and that the individual agrees to notify the Commissioner within 60 days of enrollment in such other coverage as described in § 407.55(b).

Individuals who currently have Medicare entitlement based on ESRD, and whose coverage would be terminated 36 months after the month of a successful transplant, are notified in advance of the 36-month termination by SSA. We refer to such notices as “pre-termination notices.” We plan to include information about the Part B-ID benefit in this pre-termination notice and include instructions for individuals to enroll in the Part B-ID benefit, including how to provide the required attestation.

We are proposing that beneficiaries will be able to primarily use a verbal (telephonic) attestation as part of enrolling in the Part B-ID benefit. Generally, for the verbal attestation, an individual would contact SSA, and an SSA representative, using a standard script, will convey the requirements to the individual that are in the CMS-10798 attestation form, described in § 407.59 of this proposed rule. The individual will then attest that the individual does not have

coverage under any of the specified health programs or insurance. The individual will also affirm that the statement provided was true and correct and that the individual acknowledged that there may be criminal penalties for making a false statement for purposes of obtaining these Medicare benefits. After the individual provides the oral attestation, the SSA representative will document the content of the call, and the document will be retained as required under SSA processes

Having interested beneficiaries call SSA to attest and enroll is the simplest and most efficient method, and would avoid potential delays in an individual mailing a signed written statement that could potentially result in a delay in the individual continuing to receive this vital coverage of these necessary drugs.

Using a verbal attestation and enrollment process also aligns with the President's December 13, 2021 Executive Order, titled *Executive Order on Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government*, which, among other things, directs Federal agencies to improve the public's experience of interacting with agency services. Of particular relevance, the executive order directs the Commissioner of SSA to provide a report that identifies potential opportunities for policy reforms that can support modernized customer experiences while ensuring original or physical documentation requirements remain where there is a statutory or strong policy rationale. The executive order further directs the Commissioner to, consistent with applicable law and to the extent practicable, remove requirements that members of the public provide physical signatures.

We are also proposing that individuals would be permitted to provide the attestation in writing with a pen-and-ink signature, if they choose to do so. Under our proposal, individuals could download a PDF-fillable version of an attestation form from SSA or CMS websites to

print, sign, and mail to SSA, or to call SSA to request the form in hard copy. We are further soliciting public comment on whether SSA should only accept attestations in writing with a pen-and-ink signature, and not allow an individual to attest verbally to their eligibility to enroll in the Part B-ID benefit. We are soliciting public comment on all of these proposed methods of attestation, and other potential methods such as electronic submission, submission by fax, or a signed document.

We are proposing to rely on enrollee attestations to ensure eligibility for the Part B-ID benefit, and we will monitor developments in the Part B-ID benefit program and take appropriate action to address any potential areas of concern, including with respect to inaccurate attestations or other conditions involving ineligible individuals enrolling or remaining enrolled in the Part B-ID benefit. We will continue to evaluate opportunities to enhance our oversight to ensure compliance with the eligibility requirements on an ongoing basis. We specifically request public comments on whether additional procedures would be helpful or necessary to ensure the integrity of this program. Upon receipt of public comment, CMS will consider if proposals received would need to be set out in future notice-and-comment rulemaking prior to implementation.

As mentioned previously, we are proposing to establish the eligibility criteria for the Part B-ID benefit in new § 407.55, entitled “Eligibility to enroll.” Specifically, in § 407.55(a), we propose that an individual would be eligible to enroll in, be deemed enrolled, or re-enroll in the Part B-ID benefit if their Part A entitlement ends at the end of the 36th month after the month in which the individual received a successful kidney transplant, as set out under revised § 406.13(f)(2), and discussed in section II.B.5 of this proposed rule.

The types of coverage that would make an individual ineligible for the Part B-ID benefit are specified in section 1836(b)(2)(A)(i) through (v) of the Act. Specifically, the Act requires

that individuals shall not be eligible for enrollment in the Part B-ID benefit during any period the individual is:

- Enrolled in a group health plan or group or individual health insurance coverage, as such terms are defined in section 2791 of the Public Health Service Act;
- Enrolled for coverage under the TRICARE for Life program under section 1086(d) of title 10, United States Code;
- Enrolled under a state plan (or waiver of such plan) under title XIX of the Act and is eligible to receive benefits for immunosuppressive drugs described in section 1836(b) of the Act under such plan (or such waiver);
- Enrolled under a state child health plan (or waiver of such plan) under title XXI of the Act and is eligible to receive benefits for such drugs under such plan (or such waiver); or
- Enrolled in the patient enrollment system of the Department of Veterans Affairs established and operated under section 1705 of title 38, United States Code and is either of the following:

++ Is not required to enroll under section 1705 of such title to receive immunosuppressive drugs described in section 1836(b) of the Act; or

++ Is otherwise eligible under a provision of title 38 of the United States Code (other than section 1710), to receive immunosuppressive drugs described in section 1836(b) of the Act.

We are proposing regulation text at § 407.55(b) that would mirror those requirements, as set out in sections 1836(b)(2)(A)(i) through (v) of the Act. Section 1836(b)(2) of the Act contains specific exceptions that prevent individuals from enrolling in the Part B-ID benefit. For some of those provisions, section 402 of the CAA includes an additional limitation that the coverage must include coverage of immunosuppressive drugs. For other coverage, the statute

does not include this limitation. When specific restrictions are included in one section of a statute but not in another, we presume that the language of the statute is intentional and deliberate with respect to adding the limitations. This is sometimes called the negative implication canon or *expressio unius est exclusion alterius*.

Other than coverage under Medicaid, child health plan coverage, or in regard to immunosuppressive drugs, an individual is eligible to receive from the Department of Veterans Affairs with or without enrolling in the system established and operated under section 1705 of Title 38, the statute does not address the level of coverage, or the benefits that must be provided under an individual's other coverage, that would make an individual ineligible for the Part B-ID benefit. Therefore, we interpret section 1836(b)(2)(A) of the Act to require that, except in the case of an individual who receives title XIX or XXI benefits under a state plan or waiver, or immunosuppressive drugs individuals are eligible to receive through the Department of Veterans Affairs with or without enrolling in the system established and operated under section 1705 of Title 38, an individual's enrollment in any other coverage specified under 1836(b)(2)(A), regardless of the scope of benefits offered to the individual under that coverage, would make the individual ineligible for the Part B-ID benefit.

As indicated previously, section 1836(b)(2)(B)(ii)(I) of the Act requires that an individual provide to the Commissioner an attestation that they are not enrolled and do not expect to enroll in such other coverage as described in section II.B.2.b. of this proposed rule, in order for SSA to determine if they are eligible for the Part B-ID benefit. Section 1836(b)(2)(B)(ii)(II) of the Act requires that individuals must also notify SSA within 60 days of enrollment in such other coverage as that would then make them no longer eligible for immunosuppressive drug coverage under the Part B-ID benefit. We propose to establish corresponding requirements in regulation

at new § 407.59. Specifically, we are proposing at § 407.59(a) that, in order to be eligible for immunosuppressive drug coverage, the individual must attest in either a verbal attestation or signed paper form provided by SSA, that they are not enrolled, and do not expect to enroll in, coverage as described in § 407.55(b). Similarly, at § 407.59(b) we are proposing that individuals must notify SSA within 60 days of enrollment in such coverage.

c. Enrollment in the Part B-ID Benefit

Section 1837(n)(1) of the Act states that any individual who is eligible for coverage of immunosuppressive drugs under section 1836(b) of the Act, that is, whose entitlement for hospital insurance benefits under part A ends by reason of section 226A(b)(2), may enroll or be deemed to have enrolled in the Part B-ID benefit as established in regulations and during an enrollment period. We are proposing in § 407.57(d) that, to enroll in the Part B-ID benefit, an individual must submit the required attestation as described in § 407.59. We will have historical information about individuals who will be eligible to enroll in the Part B-ID benefit based on their Medicare entitlement at the time of their transplant. In light of this fact, we believe that submission of an attestation and confirmation of an individual's eligibility as described previously will be sufficient for SSA to enroll individuals in the Part B-ID benefit. We are proposing in § 407.55(c) that, if SSA denies an individual's enrollment in the Part B-ID benefit, the individual will be afforded an initial determination entitlement appeal as described in § 405.904(a)(1). This will ensure that the beneficiary's statutory and due process rights will be adequately protected.

Section 1837(n)(2) of the Act provides that an individual whose entitlement for hospital insurance benefits under part A ends by reason of section 226A(b)(2) prior to January 1, 2023, may enroll in the Part B-ID benefit beginning on October 1, 2022, or the day on which the

individual first satisfies section 1836(b) of the Act, whichever is later. Section 1837(n)(3) of the Act specifies that an individual whose entitlement for hospital insurance benefits under part A ends by reason of section 226A(b)(2) on or after January 1, 2023, shall be deemed to have enrolled in the medical insurance program established by this part for purposes of coverage of immunosuppressive drugs.

We propose to establish the provisions relating to enrollment and the entitlement to the Part B-ID benefit in new § 407.57, titled “Part B-ID benefit enrollment.” Specifically, we are proposing at § 407.57(a) that an individual whose Part A entitlement ends at the end of the 36th month after the month in which the individual received a successful kidney transplant, on or after January 1, 2023, is deemed to have enrolled into the Part B-ID benefit effective the first day of the month in which the individual first satisfies the eligibility requirements proposed at § 407.55, and provides the attestation required in proposed § 407.59, prior to the termination of their Part A benefits.

In accordance with new subsections 1837(n)(2) and (3) of the Act, certain individuals have an ongoing opportunity to enroll in the Part B-ID benefit regardless of whether their entitlement under Part A ended before or after January 1, 2023. Therefore, we are proposing at § 407.57(b) that an individual whose Part A entitlement ends in accordance with revised § 406.13(f)(2) (as discussed in section II.B.5. of this proposed rule), and who meets the proposed Part B-ID benefit eligibility requirements proposed at § 407.55 and provides the attestation required in proposed § 407.59, may enroll in the Part B-ID benefit as follows:

- An individual whose entitlement ended prior to January 1, 2023, may enroll in the Part B-ID benefit beginning on October 1, 2022 or later.
- An individual whose entitlement ends on or after January 1, 2023 can enroll at any

time after such entitlement ends.

We are further proposing at § 407.57(c) that an individual who had previously enrolled in the Part B-ID benefit but whose participation in the benefit was terminated may re-enroll in the Part B-ID benefit at any time if they meet the eligibility requirements proposed at § 407.55 and provides the attestation required in proposed § 407.59. For instance, if an individual lost Part B-ID benefits because the individual had health coverage under a health program or insurance plan described in § 407.55(b), but then later lost that other coverage, the individual can re-enroll in the Part B-ID benefit. There are no late enrollment penalties assessed, regardless of when an individual enrolls or disenrolls from the benefit.

d. Effective Date of Entitlement

Provided the individual meets the eligibility requirements described at § 407.55 and provides the attestation as required under § 407.59, we are proposing the following entitlement dates in § 407.57(e):

- For individuals whose Medicare Part A entitlement based on ESRD status ends on or after January 1, 2023, and who submit the attestation required under § 407.59 before the end of the 36th month after the month in which they receive a successful kidney transplant, their entitlement begins with the month their Part A benefits under section 226A of the Act would end.
- For individuals who do not provide an attestation as part of the enrollment process for the Part B-ID benefit before their Part A entitlement under section 226A of the Act ends, but later provides an attestation, their entitlement begins with the month following the month in which the individual provides the attestation required in § 407.59.

- For individuals whose entitlement ended prior to January 1, 2023 and who submit an attestation as part of the enrollment process from October 1, 2022 through December 31, 2022, their entitlement begins January 1, 2023.

e. Termination of the Part B-ID Benefit

Under sections 1838(b) and (h)(4) of the Act, individuals are not required to enroll or remain enrolled in the Part B-ID benefit. Individuals enrolled in the Part B-ID benefit can terminate their enrollment in the Part B-ID benefit by notifying SSA that they no longer wish to participate in the Part B-ID benefit. SSA would also terminate the Part B-ID benefit under certain conditions. Consistent with these requirements, we are proposing in new § 407.62, “Termination of coverage,” that the effective date of the termination of an individual’s entitlement under the Part B-ID benefit will depend upon the conditions of his or her termination, as described in this section.

As discussed in section II.B.2.b. of this proposed rule, section 1836(b)(2)(A) of the Act requires that an individual is not eligible for the Part B-ID benefit if they are enrolled in certain other health coverage. Under proposed § 407.62(a)(1), when an individual enrolls in such other health coverage that would make them ineligible for the Part B-ID benefit as set out in § 407.55(b) and notifies the Commissioner of this health coverage consistent with § 407.59(b), their Part B-ID benefit would be terminated effective the first day of the month after the month of notification.

We are proposing at § 407.62(a)(1) that an individual may request a different, prospective termination date for the Part B-ID benefit to align with the coverage period under the other insurance plan or government program. While section 402 of the CAA does not explicitly authorize CMS to permit individuals to request a future termination date, it also does not prohibit

a beneficiary from requesting a future termination date. In these cases, if an individual chooses their Part B-ID benefit termination date, they will be able to retain the benefit up to the effective date of their new coverage, which will alleviate potential gaps or overlaps in coverage. For example, if an individual enrolls in employer coverage during an employer's open enrollment period in October, for a January 1st effective date, the individual can submit their request for termination of the Part B-ID benefit in October or November, and not lose their Part B-ID benefit prior to the January 1st effective date. If we only permitted an individual to use a default termination date (for example, termination on the first of the month after the month of notification), an individual submitting a termination notice in October or November would lose their Part B-ID benefit prior to the effective date of their new coverage. However, CMS would not permit individuals to request a future termination date that is after the effective date of enrollment in other health insurance coverage, as described in § 407.55(b), that would make them ineligible for the Part B-ID benefit. The law provides that individuals will lose their Part B-ID benefit eligibility when the individual is enrolled in certain other health coverage, and they notify the Commissioner of this other coverage within 60 days of their enrollment in such coverage. Individuals may wish to terminate Part B-ID benefits as soon as coverage is provided by another program so that they are not required to pay duplicative premiums for the same coverage. We believe this proposal will be helpful for beneficiaries as it would facilitate the coordination of benefit coverage and avoid duplicative costs for beneficiaries.

The rules for terminating Part B coverage based on a voluntary request for termination, set out in section 1838(b) of the Act, require that Part B coverage ends effective the close of the month following the month in which the notice is filed, except for an individual who loses coverage under a state buy-in agreement as described in § 407.50(b)(2)(i). For example, if an

individual submits a voluntary notice to terminate Part B April 1st, the individual's last day of Part B coverage would be May 31st. In contrast, we are proposing a shorter timeframe for effectuating termination of the Part B-ID benefit in § 407.62(a)(1), specifically that when an individual enrolls in other coverage and provides notification consistent with § 407.59(b), their enrollment in the Part B-ID benefit would end effective the first day of the month after the month they provide the required notification. For example, if an individual notified SSA on April 1st to end their Part B-ID benefit, their Part B-ID benefit will be terminated effective the first day of the month after the month of notification, May 1st. We are proposing this shorter period between notification and the end of individuals' Part B-ID coverage in order to minimize periods of overlapping coverage that could result in unnecessary and overlapping premium liability.

Although the statute requires that an individual's eligibility for the Part B-ID benefit ends at the time they enroll in prohibited coverage, SSA would need additional time upon the individual's notification of such other coverage, to effectuate the termination of the Part B-ID benefit. Therefore, the individual's eligibility would end as of the first day of the month after the month they provide the required notification. Further, although 1836(b)(2)(B)(ii) provides up to 60 days for Part B-ID beneficiaries to notify the Commissioner that the individual has enrolled in other health coverage, some individuals will want to notify the Commissioner sooner to reduce the financial responsibility for Part B-ID benefit premiums. We believe this approach would implement the requirements of section 1838(h) of the Act, which requires that the entitlement for Part B-ID beneficiaries ends when an individual enrolls in other health coverage that makes them ineligible for the Part B-ID benefit.

As discussed previously in this rule, we will continue to evaluate opportunities to enhance our oversight to ensure compliance with the Part B-ID benefit's eligibility requirements.

Therefore, we are proposing in § 407.62(a)(2) that if an individual who is enrolled in the Part B-ID benefit fails to provide the notice of other excepted health coverage, and it is determined that an individual has such other health coverage, the individual would be ineligible for the Part B-ID benefit as described in proposed § 407.55(b), and their enrollment in the Part B-ID benefit would be terminated on a prospective basis. If it is determined, through investigation, that an individual has such other coverage, and SSA terminates the individual's Part B-ID benefit, the individual will be provided notification and appeal rights, as currently established for Medicare Part B.

Specifically, we are proposing at § 407.62(a)(2) that the enrollment for an individual who enrolls in the Part B-ID benefit, but who subsequently enrolls in other health coverage as described in § 407.55(b) but does not notify SSA within 60 days consistent with § 407.59(b), the individual's Part B-ID enrollment would be terminated effective the first day of the month after the month in which SSA determines the individual is enrolled in health coverage described in § 407.55(b).

We are proposing this shorter period (as typically would occur with termination of Part B coverage), between SSA making a determination that an individual has certain other health coverage as set out in proposed § 407.55(b), and termination of the Part B-ID benefit, in order to minimize periods of overlapping coverage that could result in unnecessary and overlapping premium liability. We believe this approach would implement the requirements of section 1838(h) of the Act which requires that the entitlement for the Part B-ID benefit ends when an individual enrolls in other health coverage that makes them ineligible for the Part B-ID benefit.

However, we are proposing in § 407.62(f) that, if an individual is involuntarily disenrolled from the Part B-ID benefit based on § 407.62(a)(2), (b) or (c), they will be permitted an initial determination appeal as outlined in § 405.904(a)(1), which is consistent with existing requirements applicable to Part B coverage. This ensures that the beneficiary's statutory and due

process rights will be adequately protected. Consistent with appeals filed by individuals whose Medicare entitlement based on disability is denied or terminated, the individual would be entitled to the Medicare Part B-ID benefit while the appeal is in adjudication. CMS believes that this position lessens burden on beneficiaries by ensuring that there is no lapse in coverage for these necessary drugs.

Consistent with existing requirements applicable to Part B benefits at § 407.27(a), which state that entitlement to Part B benefits ends on the last day of the month in which an individual dies, we are proposing that entitlement to the Part B-ID benefit would end on the last day of the month in which the individual dies under new proposed § 407.62(b). Based on our experience administering the Part B program, we believe this approach is easy to understand, familiar to members of the public, fair, and administratively straightforward. Based on these facts we are proposing to apply this policy to the Part B-ID benefit as well.

In order to maintain consistency with existing Part B premium payment rules, and as established under section 1838(b)(2) of the Act and revised under section 402 of the CAA, we are proposing at § 407.62(c) that termination of the Part B-ID benefit for individuals who fail to pay their Part B-ID benefit premiums would end as set forth in 42 CFR part 408. This would include provisions governing a grace period by which premiums must be paid in order to avoid termination. Based on our experience administering the Part B program, we believe an approach that would apply the existing Part B requirements to the Part B-ID benefit would be easy to understand, familiar to members of the public, fair, and administratively straightforward.

Consistent with existing requirements applicable to Part B coverage under section 1838(b)(1) of the Act, we are proposing that an individual may request voluntary termination of the Part B-ID benefit. To voluntarily terminate their Part B-ID benefit, an individual will

provide notification to SSA. Primarily, we are proposing that an individual would contact SSA to request termination, either telephonically, or by visiting an SSA field office. We are also proposing that individuals could notify SSA in writing, by completing a CMS-1763 termination form, indicating that the individual no longer wishes to participate in the Part B-ID benefit (even if the individual does not have other health insurance coverage). Individuals could obtain a termination form (CMS-1763) from the SSA or CMS website to print, sign, and mail to SSA, or they can call SSA to request the form in hard copy. Providing options for beneficiaries to terminate their Part B-ID benefit aligns with the President's December 13, 2021 *Executive Order on Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government*, which directs Federal agencies to improve the public's experience of interacting with agency services. We are soliciting public comment on these proposed methods of attestation, and other potential methods such as electronic submission, or submission by fax. Once an individual contacts SSA to inform them that they want to disenroll from the Part B-ID benefit, their benefit would be terminated effective the first day of the month following the month in which they submit their request. Accordingly, we are proposing at new § 407.62(d) that an individual may request disenrollment at any time by contacting SSA to inform them that they no longer want to be enrolled in the Part B-ID benefit. Such individuals' enrollment would end with the last day of the month in which the individual provides the disenrollment request. Similar to the rationale for our proposals for § 407.62(b), based on our experience administering the Part B program we believe this approach would be easy to understand, familiar to members of the public, fair, and administratively straightforward. Based on these facts we are proposing to apply this policy to the Part B-ID benefit as well.

Under section 1838(h)(4) of the Act, individuals' entitlement to the Part B-ID benefit ends when an individual becomes entitled to Medicare based on age, disability, or ESRD status (see §§ 406.5, 406.12 and 406.13). Consistent with these statutory requirements, we are proposing that in such conditions individuals' entitlement to the Part B-ID benefit will terminate effective the last day of the month prior to the month in which the individual becomes entitled to Medicare based on either age, disability, or ESRD under new proposed § 407.62(e).

3. Ensuring Coverage Under the Medicare Savings Programs

The MSPs includes three primary¹³ Medicaid eligibility groups that cover the Medicare Part A and/or B premiums and sometimes cost-sharing for over 10 million low income individuals and are defined at sections 1905(p)(1) and 1902(a)(10)(E) of the Act. One MSP eligibility group is the Qualified Medicare Beneficiary (QMB) group, which provides medical assistance through coverage of Medicare Part A and B premiums and cost-sharing for certain individuals that meet specific requirements. In general, the individual must have income that does not exceed 100 percent of the federal poverty line (FPL) and resources that do not exceed three times the limit for SSI with adjustments for inflation as described in section 1905(p)(1) of the Act. A second MSP eligibility group is the Specified Low-Income Beneficiary (SLMB) group, which provides medical assistance through coverage of Part B premiums for individuals who would otherwise be eligible in the QMB eligibility group, except that their income exceeds 100 percent of the FPL and is below 120 percent of the FPL as defined at section 1902(a)(10)(E)(iii) of the Act. A third MSP eligibility group is the Qualifying Individuals (QI)

¹³ There is a fourth and much smaller MSP eligibility group that is the Qualified Disabled Working Individuals (QDWI) group, which provides medical assistance of coverage of Part A premiums for individuals who are entitled to Part A under section 1818A of the Act, and with income that does not exceed 200 percent of the FPL and whose resources do not exceed twice the maximum amount permitted under the SSI program. Section 402 of the CAA does not apply to QDWIs.

group, which provides medical assistance of coverage of Part B premiums for individuals who would otherwise be eligible in the QMB group, except that their income exceeds 120 percent of the FPL and is below 135 percent of the FPL as defined at section 1902(a)(10)(E)(iv) of the Act. Federal statute does not allow states to implement MSP eligibility criteria (that is, income and resource limits and methodologies) that are more restrictive than those federal baselines. However, through authority granted by section 1902(r)(2) of the Act, states may choose to implement income and/or resource methodologies that are more generous than the federal baselines for QMB, SLMB and QI.

As a result of changes made under section 402(f) of the CAA, low income individuals who are entitled to Medicare based on enrollment in the Part B-ID benefit may also be eligible for enrollment in QMB, SLMB, or QI MSPs for payment of some or all of their Part B-ID benefit premiums and cost-sharing.

Section 402(f) of the CAA revised section 1905(p)(1)(A) of the Act to change the definition of QMB to allow for individuals enrolled in the Part B-ID benefit to be eligible for medical assistance through Medicare cost-sharing as QMBs if they otherwise meet the income and resource limits established at 1905(p)(1)(B) and (C) of the Act. The CAA also made similar changes under section 1902(a)(10)(E)(iii) and (iv) of the Act to make medical assistance available for Medicare cost-sharing for Part B-ID benefit enrollees who qualify for the SLMB and QI eligibility groups. These changes would allow individuals enrolled in the Part B-ID benefit to attain eligibility for these MSPs for payment of their Part B-ID benefit premium and cost-sharing for QMBs, and for payment of their Part B-ID benefit premium as SLMBs and QIs, if such beneficiaries also meet the relevant income and resource criteria. We propose to codify this expansion of MSPs to apply to the Part B-ID benefit at new § 435.123 described in section

II.D.3.h. of this proposed rule.

Under section 1905(p)(1) and 1902(a)(10)(E) of the Act, as modified by section 402(f) of the CAA, individuals eligible for the Part B-ID benefit could become enrolled in MSPs for payment of the Part B-ID benefit (MSP Part B-ID) through two paths on or after January 1, 2023. First, individuals could enroll in the Part B-ID benefit and newly apply for Medicaid and be determined eligible for the QMB, SLMB, or QI eligibility groups by their state. Second, individuals who are enrolled in an MSP eligibility group and whose Medicare eligibility is based on ESRD, can transition to an MSP based on Part B-ID (MSP Part B-ID) the month after 36 months after transplant if they enroll in the Part B-ID benefit under certain conditions. In order to transition to MSP Part B-ID under this latter condition, the individual must a) return the attestation to be deemed to enroll in the Part B-ID benefit by the end of the 36th month after the month in which they receive a kidney transplant in accordance with the attestation requirements in section 1836(b)(2)(B) of the Act and b) continue to meet the other eligibility criteria for an MSP eligibility group described in section 1905(p)(1), 1902(a)(10)(E)(iii), or (iv) of the Act. We anticipate the second situation will help ensure continuity of coverage for beneficiaries, but note that continuity of coverage depends on many factors, including the timing of when an individual attests to not having other disqualifying insurance coverage under § 407.59 as well as coordination among multiple entities including states, CMS and SSA. Given its greater complexity, the second situation is the primary focus of our discussion here.

The simplest way to maintain continuity of coverage for individuals enrolled in an MSP who are losing Medicare entitlement based on ESRD status is through the Medicaid redetermination process. For full- and partial-benefit (that is, individuals enrolled only in an MSP and receiving coverage of only Medicare premiums and sometimes cost sharing) Medicaid

beneficiaries who have Medicare entitlement based on ESRD status and lose full Medicare coverage 36 months after the month in which they received a kidney transplant, this loss of full Medicare coverage would constitute a change in circumstance under § 435.916(d) even if they might obtain coverage under Medicare through enrollment in the Part B-ID benefit. Under § 435.916(d)(1), state Medicaid agencies are required to promptly redetermine an individual's eligibility for Medicaid whenever it receives information about a change in a beneficiary's circumstances that may affect their eligibility. We are providing an overview of how the Medicaid redetermination process will operate under the existing Medicaid regulations for both full- and partial-benefit Medicaid beneficiaries who have Medicare entitlement based on ESRD status and lose full Medicare coverage. However, for clarity, we want to highlight up front that individuals who remain or become full-benefit Medicaid beneficiaries after this redetermination process will not be eligible for the Part B-ID benefit, as explained in this section.

During this redetermination process, under §§ 435.916(b) and 435.911, individuals who are already eligible for a full-benefit Medicaid eligibility group, such as those receiving Supplemental Security Income (SSI)¹⁴ would still retain their Medicaid eligibility as long as there are no other disqualifying changes to income or disability status. This is true of the redetermination process for all individuals who are eligible for more than one eligibility group in Medicaid. If the change in circumstance only ends the individual's eligibility for one eligibility group but not the other, the individual remains eligible for the eligibility group for which they still qualify. Even if the individual was not eligible previously for a full-benefit Medicaid eligibility group, if the individual nonetheless qualifies for a full-benefit Medicaid eligibility

¹⁴ In most states, receipt of SSI automatically qualifies an individual for Medicaid. See § 435.120.

group (for example, the adult group) after the redetermination, the state must enroll the individual in that group per §§ 435.916(f) and 435.911.

We anticipate that individuals who are eligible for a full-benefit Medicaid eligibility group would not be eligible for the Part B-ID benefit, because all states currently opt to cover immunosuppressive drug coverage for all full-benefit Medicaid eligibility groups and by virtue of having such drug coverage under Medicaid they would be ineligible according to section 1836(b)(2)(A)(iii) of the Act.

On the other hand, if the individual is not eligible for Medicaid on any basis, the state is required to screen the individual for potential eligibility for other insurance affordability programs as defined in § 435.4 in accordance with § 435.1200(e), as required under § 435.916(f). This would include referring the individual to an Exchange to determine whether the individual is eligible for enrollment in a Qualified Health Plan with Advance Premium Tax Credit (APTC), cost sharing reductions (CSRs) or both as described in § 435.4. We also encourage states to inform the beneficiary of the Part B-ID benefit and coordinate with SSA, State Health Insurance Assistance Programs (SHIPs), and beneficiary groups, among others, to help individuals complete the telephonic Part B-ID benefit attestation, and provide other personalized assistance if the individual does not qualify for full-benefit Medicaid or the Exchange with either APTC or CSRs. We note that if the individual enrolls in an Exchange plan, it will make them ineligible for the Part B-ID benefit as set out in § 407.55(b). If the individual has already enrolled in the Part B-ID benefit prior to enrollment in the Exchange, they will need to notify SSA of this health care coverage in the Exchange consistent with § 407.59(b).

If the individual does not ultimately enroll in the Part B-ID benefit, the state would terminate MSP enrollment because individuals must have Part A entitlement or be enrolled in the

Part B-ID benefit to be eligible for the MSPs under sections 1905(p)(1)(A) and 1902(a)(10)(E)(iii) and (iv) of the Act. Prior to termination, states must provide affected beneficiaries with advance notice and an opportunity for a fair hearing in accordance with § 435.917 and part 431, subpart E.

If, as a result of the redetermination process that must be completed prior to termination under § 435.916(f), the state identifies that the individual has completed the required attestation and would be enrolled in the Part B-ID benefit the month after Medicare entitlement based on ESRD ends (the end of the 36th month after the month in which the individual received a kidney transplant), the state must maintain the individual in the appropriate MSP eligibility group for payment of Part B-ID benefit premiums and, if eligible, cost-sharing, provided there are no other disqualifying changes in the income and resources of the individual under section § 435.911.

As noted previously, the changes to section 402(f) of the CAA expand the definition of QMB, SLMB, and QI to allow individuals to qualify for those MSPs based on their enrollment in the Part B-ID benefit and meeting the income and resource standards of MSPs. As such, as part of considering all bases of eligibility in the redetermination process under § 435.916(f)(1), states must consider the revised eligibility criteria in section 402(f) of the CAA and enroll individuals in MSP Part B-ID benefit who are enrolled in the Part B-ID benefit and meet the income and resource criteria for MSPs.

If an individual was enrolled in an MSP while entitled to Medicare on the basis of ESRD, their continued enrollment in MSPs for the Part B-ID benefit will ultimately depend on how quickly the state completes its redetermination, whether the individual has full Medicaid benefits (and whether the State plan would cover immunosuppressive drugs for the individual), and whether the individual enrolls in the Part B-ID benefit. If the state does not complete the

redetermination process prior to the end of the 36th month after the month in which the individual received a kidney transplant, when an individual's Medicare entitlement based on ESRD status ends under section 226A(b)(2) of the Act, and the individual had full Medicaid plus an MSP prior to the point at which their Medicare entitlement ends according to section 226A(b)(2) of the Act, the individual would retain full Medicaid until the redetermination is complete per § 435.930(b), but would lose MSP coverage when Medicare entitlement based on ESRD Medicare coverage expires. While states are required to continue furnishing Medicaid until the state determines an individual ineligible for Medicaid under § 435.930(b), the only medical assistance provided for MSPs is payment of Medicare premiums and sometimes cost-sharing. As such, when Medicare entitlement ends, states stop providing MSP coverage because the individual no longer has a Medicare benefit for which they owe premiums, deductibles, coinsurance and copayments. Beneficiaries losing MSP coverage under these conditions may remain eligible for Medicaid on another basis, and states must furnish the Medicaid coverage for which they are eligible until they are found to be ineligible under § 435.930(b).

If the state does not complete the redetermination process by the end of the 36th month after the month in which the individual received a kidney transplant, when Medicare entitlement based on ESRD status would end, and the individual is enrolled only in an MSP and *does* complete the Part B-ID benefit attestation prior to losing Medicare based on ESRD status, then, under § 435.930(b), the individual would maintain enrollment in their current MSP until the redetermination is complete, and the MSP would cover the appropriate costs for the Part B-ID benefit. In this scenario, once CMS receives enrollment confirmation of the individual in the Part B-ID benefit from SSA, CMS systems will automatically switch the individual from state buy-in for Part B to the Part B-ID benefit buy-in and alert the state of the individual's new

enrollment and billing status. The reason for the difference in the outcome when the individual returns the attestation is that under § 435.930(b), the state must continue furnishing MSP because there would be a Medicare benefit to wrap around through coverage of premiums, deductibles, coinsurance and copayments.

If the state does not complete the redetermination process by the end of the 36th month after the month in which the individual received a kidney transplant, when Medicare entitlement based on ESRD status would end, and the individual is enrolled only in an MSP and *does not* complete the Part B-ID benefit attestation prior to losing Medicare entitlement based on ESRD status, then the individual would not be entitled to coverage of immunosuppressive drugs therapy under section 1836(b)(2)(B) of the Act or state payment of the premiums for the Part B-ID benefit because enrollment in the Part B-ID benefit is a pre-requisite to state payment of premiums under section 402(f) of the CAA.

After a kidney transplant, individuals must diligently take immunosuppressive drug therapy in order to avoid the rejection of the kidney.¹⁵ In order to prevent gaps in coverage of such medication when individuals transition off Medicare entitlement based on ESRD status, for partial-benefit Medicaid beneficiaries (beneficiaries enrolled in an MSP and not full-benefit Medicaid), states will need to complete redeterminations regarding Medicaid eligibility under § 435.916(d) before individuals' Medicare eligibility based on ESRD status ends. While we note that these individuals could continue coverage under the MSP Part B-ID benefit if they complete the attestation, many of these individuals will be eligible for full-benefit Medicaid under the adult group described at §435.119 in all states that expanded Medicaid since the MSPs generally have an income limit up to 135 percent of the FPL and the adult group has an income

¹⁵ <https://www.medicare.gov/Pubs/pdf/10128-medicare-coverage-esrd.pdf>.

limit up to 138 percent of the FPL. Enrolling individuals in adult group coverage at the outset instead of enrolling them retroactively is vastly preferable -- both to provide immediate coverage of their health coverage needs and to reduce administrative burden. Additionally, if these individuals are ultimately enrolled retroactively in full-benefit Medicaid after enrolling in the Part B-ID benefit—and these Medicaid benefits continue to include coverage of immunosuppressive drugs for the individual, the individuals will need to inform SSA that they have other insurance coverage in order for SSA to terminate them from the Part B-ID benefit in accordance with §407.62. These individuals will also need to ask their providers to submit all of their bills to Medicaid for payment beginning from the date Medicare entitlement based on ESRD status ended until the date of the new notice of determination of full Medicaid. For any immunosuppressive drugs received during that time, the individuals would need to ask their pharmacy to bill Medicaid for any Medicare copays paid by the individual because Medicaid would pay secondary to Medicare. As such, we are strongly recommending that states start an early advance redetermination process for those partial-benefit beneficiaries whose Medicare entitlement is based on ESRD status and who receive kidney transplants. As noted previously, during this redetermination process, we encourage states to reach out to individuals who are likely eligible for the MSP Part B-ID benefit to explain the Part B-ID benefit and if necessary, coordinate with SSA, SHIPs and beneficiary advocates to help them submit the attestation to enroll in the Part B-ID benefit, which will assist the state in enrolling them in the appropriate MSP. We are also exploring steps to conduct outreach and education for beneficiaries and multiple external partners, including those who regularly assist beneficiaries with health insurance counseling, regarding the most appropriate coverage options for MSP beneficiaries transitioning off Medicare entitlement based on ESRD. Additionally, CMS will be engaged and

able to assist beneficiaries in assessing their health care options and enrolling in the Part B-ID benefit as needed. We welcome comments regarding steps CMS can take to assist beneficiaries and promote awareness of coverage choices upon loss of the ESRD Medicare benefit with the goal of minimizing gaps in coverage and ensuring enrollment in the most comprehensive benefit available to them.

Both the early redetermination process and the outreach effort to beneficiaries will help reduce the risk of gaps in coverage for immunosuppressive drugs for this vulnerable beneficiary population.

We anticipate this early redetermination process and outreach effort will improve the customer service experience of kidney transplant recipients, consistent with *the Executive Order on Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government*. We also believe it will have a positive health equity impact consistent with the *Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*. Finally, by helping to avoid gaps in Medicaid and Marketplace coverage, it is consistent with the *Executive Order on Strengthening Medicaid and the Affordable Care Act*. In general, individuals with ESRD are more likely to be from racial or ethnic minority groups.¹⁶ Additionally, individuals who are younger, poorer and less educated have more difficulty affording transplant medication, which has led to lower rates of graft survival among those populations.¹⁷ Making immunosuppressive drugs more affordable to

¹⁶ See <https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease> discussing that ESRD prevalence is about 3.7 times greater in African Americans, 1.4 times greater in Native Americans, and 1.5 times greater in Asian Americans.

¹⁷ Gordon, Elisa J., Prohaska, Thomas R., and Sehgal, Ashwin R. *The Financial Impact of Immunosuppressant Expenses on New Kidney Transplant Recipients* *Clin Transplant* 2008: 22, 736. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2592494/>.

individuals through MSPs would improve lower income individuals' access to immunosuppressive drugs critical to prevent transplant failure.

As discussed previously, if an individual who had MSP coverage while entitled to Medicare based on ESRD status fails to enroll in the Part B-ID benefit after losing Medicare entitlement based on ESRD status, by the end of the 36th month after the month in which the individual received a kidney transplant the individual would also lose access to the MSPs after the state provides appropriate notice and fair hearing rights. However, an individual may re-apply for the MSPs if they later enroll in the Part B-ID benefit under section 402(f) of the CAA. Moreover, if an individual did not previously enroll in an MSP while entitled to Medicare based on ESRD status, once they enroll in the Part B-ID benefit they may apply for and enroll in an MSP provided they meet the applicable eligibility criteria.

We note that states will be required to enroll individuals in an MSP if they are enrolled in the Part B-ID benefit, apply for an MSP, and meet the income and resource requirements of an MSP. As explained previously, section 402(f) of the CAA modified the eligibility requirements for QMB, SLMB, and QI at 1905(p)(1) and 1902(a)(10)(E)(iii) and (iv) of the Act to make those MSPs available to individuals enrolled in the Part B-ID benefit. Thus, states must make an MSP eligibility determination for individuals who enroll in the Part B-ID benefit and apply for an MSP. If a state determines that individuals enrolled in the Part B-ID benefit meet the income and resource requirements for an MSP, the state must enroll those individuals in an MSP to pay for Part B-ID benefit premiums and cost-sharing, as applicable.

Finally, we note that individuals enrolled in the Part B-ID benefit and an MSP would lose coverage under both programs in any of four conditions described in §§ 407.62(a),(b),(d), and (e). Specifically, an individual's enrollment in both the MSPs and the Part B-ID benefit would

end in accordance with § 407.62 if the individual (1) enrolls in other health insurance that makes them ineligible for the Part B-ID benefit as described in § 407.55(b); (2) becomes eligible for Medicare Part A on the basis of age, disability or ESRD status; (3) voluntarily terminates coverage; or (4) dies. In order to be eligible for MSPs, individuals must be entitled either to Part A under section 1905(p)(1)(A) and 1902(a)(E)(10) or the Part B-ID benefit as described in section 402(f) of the CAA. When individuals lose their entitlement to Medicare, they are terminated from MSPs after notice and fair hearing rights have been provided in accordance with § 435.917 and part 431, subpart E. As such, when individuals who are enrolled in an MSP for payment of Part B-ID benefit lose their underlying basis for enrollment in the Part B-ID benefit, they would no longer qualify for an MSP under section 402(f) of the CAA. In the first instance, if the individual is enrolled in an MSP based on his or her enrollment in the Part B-ID benefit, and they obtain other coverage that would make the individual ineligible for the Part B-ID benefit under section 1836(b)(2) of the Act, they would also no longer qualify for the MSP. In the second condition, if the individual is enrolled in an MSP based on his or her enrollment in the Part B-ID benefit, and they become entitled to Medicare based on age, disability or ESRD status, the Part B-ID benefit ends under section 1838(h)(4) of the Act; they would no longer be eligible for the MSP Part B-ID benefit. However, assuming there were no other disqualifying conditions, the individual would continue to be eligible for an MSP, which would then pay the Medicare Part B premiums and, if applicable, Part A premiums and cost-sharing on behalf of the individual, rather than the Part B-ID benefit premium. In the third condition, if the individual is enrolled in an MSP based on enrollment in the Part B-ID benefit and the individual voluntarily disenrolls from the Part B-ID benefit in accordance with section 1838(b)(1) of the Act, the individual would also become ineligible for the MSP Part B-ID benefit. Finally, if the individual

is enrolled in an MSP based on his or her enrollment in the Part B-ID benefit and the individual dies, he or she is ineligible for the Part B-ID benefit under § 407.27(a), and would no longer be eligible for an MSP.

4. Part B-ID Benefit Premiums

The Secretary of the Department of Health and Human Services (HHS) is required by section 1839 of the Act to announce the Part B monthly actuarial rates for aged and disabled beneficiaries. These amounts, according to actuarial estimates, will equal, respectively, one half of the expected average monthly cost of Part B for each aged enrollee (age 65 or over) and one half of the expected average monthly cost of Part B for each disabled enrollee (under age 65). The standard monthly Part B premium represents roughly 25 percent of estimated program costs for aged enrollees and is calculated to be 50 percent of this aged actuarial rate, plus the \$3.00 repayment amount required under current law. (Although the costs to the program per disabled enrollee are different than for the aged, the statute provides that the two groups pay the same premium amount.) Premiums may be further adjusted based on an individual's conditions, such as based on late enrollment or reenrollment (§ 408.22), the income-related monthly adjustment amount (§ 408.28), or for beneficiaries subject to non-standard premiums (§ 408.20).

We are proposing to create a new paragraph § 408.20(f) to implement the requirements established under section 1839(j) of the Act and propose to modify other existing requirements for Part B premiums found in 42 CFR part 408 as required by statute for the Part B-ID benefit. We are proposing in § 408.20(f)(1), that beginning in 2022, as required by new section 1839(j) of the Act, the Secretary would determine and promulgate a monthly premium rate in September of each year for the succeeding calendar year for individuals enrolled only in the Part B-ID benefit. Such premium would be equal to 15 percent of an actuarial rate that represents 100

percent of the estimated average monthly cost of Part B for each aged enrollee (age 65 or over). This amount is then rounded to the nearest \$0.10.

The standard 20 percent coinsurance and annual Part B deductible would apply to the Part B-ID benefit. As required under new section 1839(j) of the Act and other conforming changes of the Act, we are proposing in § 408.20(f)(2)(i) that the Part B-ID benefit premium would be subject to adjustments specified in §§ 408.20(e) (Nonstandard premiums for certain cases), 408.27 (Rounding the monthly premium), and 408.28 (Increased premiums due to the income-related monthly adjustment amount (IRMAA)). In addition, under section 1839(j) of the Act, the Part B-ID benefit premiums are also not subject to the LEP. Accordingly, we are proposing to provide in section § 408.20(f)(2)(ii) that premiums for the Part B-ID benefit would not be subject to increased premiums for late enrollment or reenrollment under § 408.22.

Section 1840 of the Act requires that for individuals receiving monthly railroad retirement or Social Security benefits or a civil service annuity, payment for Part B premiums for those individuals must generally be deducted from those payments. In light of these requirements, we are proposing in § 408.20(f)(3) that the collection of premiums for the Part B-ID benefit would follow the existing requirements governing the collection of Part B premiums set out in § 408.6 and part 408, subpart C of title 42. Under those provisions, if a beneficiary is receiving a monthly Social Security or Railroad retirement benefit, or civil service annuity, their Part B premium must typically be deducted from that monthly benefit. In conditions where an individual does not receive benefits of the sort described previously, premiums must be paid by direct remittance; in such cases CMS bills the beneficiary directly.

5. Conforming Changes

Certain individuals are entitled to hospital insurance coverage under Medicare Part A on the basis of ESRD, as provided under section 226A of the Act. Section 406.13(f)(2) currently specifies that the period of entitlement to Medicare Part A for individuals whose Medicare entitlement is based on ESRD ends with the end of the 36th month after the month in which the individual has received a kidney transplant. We are proposing to revise § 406.13(f)(2) to provide that beginning January 1, 2023, individuals no longer entitled to Part A benefits due to their coverage ending at the end of the 36th month after the month in which the individual received a kidney transplant, may be eligible to enroll in Part B solely for purposes of coverage of immunosuppressive drugs as described in § 407.55.

Medicare Part B covers health services including prescription drugs used in immunosuppressive therapy furnished to an individual who receives an organ transplant for which Medicare payment is made. Section 410.30(b) currently lays out the requirements governing eligibility for coverage of prescription drugs used in immunosuppressive therapy, stating that coverage is only available for prescription drugs used in immunosuppressive therapy, furnished to an individual who received an organ or tissue transplant for which Medicare payment is made, and provided the individual is eligible to receive Medicare Part B benefits. Chapter 15 of the Medicare Benefit Policy Manual, section 50.5.1¹⁸, lists some of the Food and Drug Administration (FDA)-approved, specifically labeled immunosuppressive drugs. They are: Sandimmune (cyclosporine), Imuran (azathioprine), Atgam (antithymocyte globulin), Orthoclone OKT3 (Muromonab-CD3), Prograf (tacrolimus), Celicept (mycophenolate mofetil, Daclizumab (Zenapax); Cyclophosphamide (Cytoxan); Prednisone; and Prednisolone. However, this is not

¹⁸ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>

intended to be an all-inclusive list and is subject to change. The manual guidance states that CMS “*expects contractors to keep informed of FDA additions to the list of the immunosuppressive drugs.*” This expectation would carry over to the Part B-ID benefit.

Medicare Administrative Contractors have issued Local Coverage Determinations on this topic and, generally speaking (using Local Coverage Determination #L33824 as an example¹⁹), covered immunosuppressive drugs are oral tablets or capsules. However, certain immunosuppressive drugs may be intravenously infused or intramuscularly injected. The majority of the immunosuppressive drugs have generic equivalents; however, certain newer agents remain available as brand only.

A beneficiary will typically gain access to the drug through a pharmacy, where applicable supplying fees to pharmacies (as described in section 1842(o)(6) of the Act) are paid. However, where the conditions require an infused or injectable immunosuppressive therapy, these would be administered in the physician office or outpatient setting. In this case of Part B-ID, only the cost of the drug would be covered (not the service of administration). Immunosuppressive therapies covered under Part B are paid based on pricing methodology in 1847A of the SSA (typically, this is an ASP-based payment limit). Payment limits for many immunosuppressive therapies can be found on the ASP Drug Pricing File²⁰, which is updated quarterly. Cost sharing is typically 20 percent.

We are proposing to revise § 410.30(b) to specify that beginning January 1, 2023, individuals who meet the requirements as specified in section § 407.55 are eligible to receive Medicare Part B benefits for purposes of § 410.30(b).

¹⁹ <https://www.cms.gov/medicare-coverage-database/search.aspx>

²⁰ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice>

An individual is eligible for enrollment into a Part D plan if certain conditions are met, as set out in section 1860D-1(a) of the Act. Section 423.30(a)(1)(i) of the regulations establishes that an individual is eligible for Part D if they have Medicare benefits under Part A or are enrolled in Medicare Part B. Section 423.30(a)(1)(i) would be revised to specify that an individual is eligible for Part D if they are entitled to Medicare benefits under Part A or enrolled in Part B, but does not include an individual enrolled solely in Part B for coverage of immunosuppressive drugs under § 407.1(a)(6).

Section 402 of the CAA states that the Secretary may conduct public education activities to raise awareness of the availability of more comprehensive, individual health insurance coverage (as defined in section 2791 of the Public Health Service Act) for individuals eligible under section 1836(b) of the Act to enroll or to be deemed enrolled in the medical insurance program established under this part for purposes of coverage of immunosuppressive drugs.

As a part of implementation, CMS will conduct education and outreach across the broad span of partners (that is, beneficiary advocacy groups, providers, associations, etc.) to ensure awareness and understanding of this benefit. Also, we note that all appropriate beneficiary notices, such as the Medicare based on ESRD pre-termination notice, (discussed in this proposed rule), the notice that will be provided to individuals who were previously terminated from Medicare based on ESRD to inform of the Part B-ID benefit, as well as the annual notice to individuals that have the Part B-ID benefit, will include information on the availability of, and contact information for, other comprehensive coverage that an individual may want to explore, such as Marketplace or Medicaid coverage. Additionally, as discussed in section II.B.3, we are encouraging states to provide education and assistance to individuals as part of the Medicaid redetermination process. We are also exploring steps to conduct outreach and education for

beneficiaries and multiple external partners, including those who regularly assist beneficiaries with health insurance counseling, regarding the most appropriate coverage options for MSP beneficiaries transitioning off Medicare entitlement based on ESRD.

We welcome comments on our proposals implementing the Part B-ID benefit for eligible individuals.

C. Proposal on Simplifying Regulations Related to Medicare Enrollment Forms (§ 406.7 and 407.11)

We propose to revise §§ 406.7 and 407.11 to remove references to specific forms that are used to enroll in Medicare Part A and Part B, respectively. This is an administrative change that would simplify existing regulations and would have no impact on current eligibility requirements or enrollment processes or the use or availability of these forms. We propose to continue to update our forms, including form numbers, and the conditions in which each form is used, through subregulatory guidance because these are procedural, and not substantive rules.

Identifying each form in regulation as we have historically done means that rulemaking is required to change the description of those forms or the numbers of the forms, which in turn makes it challenging for CMS and SSA to update forms or to adopt new forms or new applications of existing forms as necessary. For example, the CMS-18-F-5 is currently described in §§ 406.7 and 407.11 as an application for Part A and Part B for individuals who are not eligible for benefits through Social Security or under the Railroad Retirement Act. CMS and SSA decided that the form should be used for all Part A enrollments irrespective of individual enrollee's eligibility for retirement benefits. OMB approved the use of the form under this new scope. However, in order to carry out this change, it would be necessary to revise our regulations at §§ 406.7 and 407.11 to reflect the revised uses of the form. Similarly, listing the

forms in regulation also means that rulemaking is necessary to update our regulations when forms are removed from use. Currently § 407.11 lists the forms 40-D and 40-F, which are obsolete.

We are proposing to change our regulations in §§ 406.7 and 407.11 to remove all references to specific enrollment forms that are used to apply for entitlement under Medicare Part A and enrollment under Medicare Part B. Specifically, we are revising § 406.7 to provide that forms used to apply for Medicare entitlement are available free of charge by mail from CMS or at any Social Security branch or district office or online at the CMS and SSA websites. We are also proposing to make technical edits to the text to state that an individual who files an application for monthly Social Security cash benefits as defined in § 400.200 to apply also applies for Medicare entitlement if he or she is eligible for hospital insurance at that time. Similarly, we are revising § 407.11 to provide that forms used to apply for enrollment under the supplementary medical insurance program are available free of charge by mail from CMS, or at any Social Security branch or district office and online at the CMS and SSA websites. These changes would allow both agencies to quickly adapt to the needs of beneficiaries by adding, removing, or updating forms as necessary. We believe that the form numbers and descriptions would be disseminated most appropriately through sub-regulatory guidance.

We are also proposing a technical change in the last paragraph of § 406.7 to refer to “monthly Social Security benefits” instead of “monthly social benefits.”

D. Modernizing State Payment of Medicare Premiums (§§ 400.200, 406.21, 406.26, 407.40 through 407.48, 431.625, 435.4, 435.123 through 126)

CMS seeks to modernize the Medicare Savings Programs through which states cover Medicare premiums and cost-sharing. As part of these efforts, we are proposing to update the

various federal regulations that affect a state's payment of Medicare Part A and B premiums for beneficiaries enrolled in the Medicare Savings Programs and other Medicaid eligibility groups. Specifically, CMS is proposing updates at (1) § 406.21, which was last revised in 1996; (2) §§ 406.26, and 407.40 through 48, which were last revised in 1991;²¹ (3) § 431.625, which was last revised in 1988; and (4) § 400.200, which was last revised in 1983. We also propose to add new §§ 435.123 through 435.126 and to revise § 435.4 to codify in CMS Medicaid regulations the Medicare Savings Programs under section 1902(a)(10)(E) of the Act.

Our proposed rulemaking includes policy proposals to modernize the state buy-in program and technical updates to reflect statutory changes over the last three-plus decades. We also propose to codify in the regulations certain administrative practices that have evolved over the years and seek comment on alternative policies we considered that might be adopted in a final rule based on comments received. The provisions described in this section of the rule would clarify minimum requirements for the state payment of Medicare premiums and options for states to streamline eligibility and enrollment in the Medicare Savings Programs and other Medicaid eligibility groups. We believe that our proposals would improve the customer service experience of dually eligible beneficiaries under *Executive Order on Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government*. We anticipate our proposals will also advance health equity by improving low income individuals' access to continuous, affordable health coverage and use of needed health care consistent with *Executive*

²¹ We note that CMS made a minor technical update to § 407.42 to remove the reference to the obsolete regulatory provision, § 435.114 (Individuals Who Would Be Eligible for AFDC Except for Increased OASDI in the Income Under Pub. L. 92-336) in the November 30, 2016 **Federal Register** (81 FR 86382), entitled "Medicaid and Children's Health Insurance Programs: Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Other Provisions Related to Eligibility and Enrollment for Medicaid and CHIP," (hereinafter referred to as the November 2016 final rule).

Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.

1. State Plan Amendment as Agreement between State and CMS (§ 407.40)

Section 1843 of the Act provides for “agreements” between a state Medicaid agency and the Secretary to facilitate the payment of Part B premiums for Medicare-eligible Medicaid beneficiaries (“buy-in agreements”). All states currently have elected to enter into such agreements, and process Part B premium payments as provided under section 1843 of the Act. Under section 1818(g) of the Act, starting January 1, 1990, states could expand their buy-in agreements to enroll Qualified Medicare Beneficiaries (QMBs) in Premium Part A, with the state paying the Part A premiums on their behalf. As of the date of this proposed rule, 36 states and the District of Columbia include the payment of Part A premiums for QMBs in their buy-in agreement (“Part A buy-in states”), but 14 states use the group payer arrangement to pay Part A on behalf of QMBs under § 406.32(g) (“group payer states”).²²

To execute agreements under section 1843 of the Act, the Secretary and states initially signed free-standing, written agreements that defined the then-scope of a state’s buy-in agreement for Part B and bind the states to follow federal regulations and guidance under section 1843 of the Act. However, none of these original signed agreements have been updated for decades, despite ensuing federal statutory requirements and agreed-upon changes to state or federal buy-in policy. In fact, there have been no amendments since 1992 to any of the free-standing written agreements currently in place. None of the freestanding written agreements were modified to include buy-in for premium Part A under section 1818(g) of the Act. For

²² The group payer arrangement allows certain parties (for example, states) to pay Part A premiums for a class of beneficiaries. See Program Operations Manual System (POMS) HI 01001.230 Group Collection-General at <http://policy.net.ba.ssa.gov/poms.nsf/lrx/0601001230>.

example, as stated in the preamble to final rule with comment period published in the August 12, 1991 **Federal Register** (56 FR 38074), entitled “Medicare and Medicaid; Eligibility for Premium Hospital Insurance; State Buy-In Agreements,” (hereinafter referred to as the August 1991 final rule), states were deemed by regulation to include Part B and premium Part A coverage for QMBs in their buy-in agreement unless they opted out for either or both Parts, even though the agreements themselves were not amended to reflect this. Likewise, the existing free-standing agreements do not expressly provide for Part B coverage for two other Medicare Savings Program groups – the Specified Low-Income Beneficiary (SLMB) and Qualifying Individual (QI) groups – although, as explained in section II.D.5. of this proposed rule, CMS subregulatory guidance and operational policy consider all agreements to incorporate these eligibility groups. In lieu of amending the decades-old free-standing written agreements, CMS and states have used Medicaid state plans and state plan amendments (SPAs) to document current state buy-in election choices and modifications. We believe that the vast majority of current Medicaid state plans accurately reflect the buy-in coverage groups and elections agreed upon by CMS and the states.²³ However, there are provisions in the free-standing buy-in agreements that are not reflected in these state plan provisions, and these non-current agreements have never officially been superseded. As such, for a complete picture of the full obligations a state has agreed to under section 1843 of the Act, it is necessary to review both the free-standing agreement and deemed amendments to this agreement done through the SPA process. This is not an efficient or effective way to reflect the state’s obligations under its buy-in agreement with CMS.

²³ States generally include this information at section 3.2 of the state plan template, under “Coordination of Medicaid with Medicare and Other Insurance of their state Medicaid Plan.”

Section 1902(a)(4) of the Act authorizes the Secretary to specify “methods of administration” states should adopt under their Medicaid state plans that are “found by the Secretary to be necessary for proper and efficient administration” of the state’s Medicaid program. We propose to use this authority to amend the definition of a state buy-in agreement at § 407.40(b) by specifying that state plan provisions addressing what a state has agreed to under sections 1843 and 1818(g) constitute the state’s buy-in agreement for purposes of those sections, including the scope of a state’s buy-in practice, and that all aspects of a state’s buy-in agreement with the Secretary, including what is set forth in the original buy-in agreements that is not currently in the state plan, should be set forth in the state’s Medicaid state plan. The state’s submission of a SPA addressing what it is agreeing to under sections 1843 and/or 1818(g), and CMS’s approval, would under our proposal constitute the “agreement” between the two parties for purposes of sections 1843 and 1818(g). This proposal would codify CMS’ long-standing practice of effectuating changes in buy-in policy through the Medicaid state plans, rather than through the free-standing written agreements originally executed with each state, and also consolidate all terms of the buy-in agreement authorized or modified under sections 1843 and 1818(g) in one “agreement” between the parties in the form of submission and approval of relevant SPAs.

If this proposal is finalized, the free-standing buy-in agreements would be superseded by provisions related to buy-in practices within a state Medicaid plan, and, to the extent that any states seek to update their state plans, we would work with states to modify their state plans as needed and reiterate that they bind the state to follow Medicare regulations and guidance under sections 1843 and 1818(g) of the Act.

We believe our proposal would help remove ambiguity about the prevailing buy-in policies in each state and foresee no negative impacts or substantive changes for coverage policies or buy-in processes. We welcome comments on whether there are benefits to maintaining the free-standing buy-in agreements or other unintended effects of our proposal. Because approved state plan provisions addressing what a state has agreed to under sections 1843 or 1818(g) or both would constitute the buy-in agreement referenced in those sections, and there are existing mechanisms for: (1) a state to modify or terminate this buy-in agreement through the State plan amendment process; and (2) CMS to enforce under section 1904 of the Act compliance with the state plan requirements that reflect a state's buy-in agreement, we are also proposing to delete § 407.45, which currently addresses a decision by a state to terminate its buy-in agreement, and CMS termination of a state's buy-in agreement for a state failure to comply with it.

2. Limiting State Liability for Retroactive Changes and Related Updates (§ 407.47)

Under section 1843 of the Act, states must pay Part B premiums for any individual starting the first month they are both a member of the state buy-in coverage group specified in the buy-in agreement and eligible for Part B.²⁴ In some instances, SSA determines Medicaid beneficiaries eligible for Medicare for a retroactive period. This generally occurs when an

²⁴ For individuals enrolled in Medicaid eligibility groups related to cash assistance and QMB, SLMB, and QI, § 407.47(b) and (c) specify that the buy-in coverage period begins the later of the *first month* the individual is a member of a buy-in coverage group (that is, the effective date of the individual's underlying coverage) and eligibility for Part B, or the effective date of the buy-in agreement or modification that includes the buy-in coverage group to which the individual belongs. However, for individuals enrolled in one of the other Medicaid eligibility groups, § 407.47(c) specifies that the buy-in coverage period starts the later of the *second month* the individual meets the requirements for both eligibility in the buy-in coverage group and Medicare Part B, or the effective date of the buy-in agreement or modification that includes the buy-in coverage group to which the individual belongs.

individual under age 65 who files a claim for disability benefits at SSA²⁵ receives a favorable social security disability insurance (SSDI) award multiple years after the initial application, and SSA determines the individual eligible for SSDI benefits at or up to 12 months prior to the point of application, even though they were not able to receive SSDI payments timely because eligibility had not yet been determined. Individuals entitled to SSDI become entitled to premium-free Medicare Part A after 24 months of entitlement to SSDI. As described in the examples that follow, on occasion, an individual's favorable determination of SSDI is retroactive more than 24 months, in which case the determination of SSDI eligibility for a retroactive period for the individual means that the individual's Part A entitlement is retroactive as well. The individual is also retroactively eligible to enroll in Part B over this period.²⁶ However, SSA does not enroll the individual in Part B for the past months unless the individual pays SSA a lump sum amount reflecting the total costs of Part B premiums the individual would have paid had they been enrolled in Part B during that time or the individual is a member of the state buy-in coverage group as explained in this section of this rule.

Retroactive Medicare Part A entitlement for a Medicaid-eligible individual can have multiple implications for state Medicaid agencies. First, states may, under their buy-in agreement, be liable for Medicare Part B premiums for the retroactive period. If a state learns that SSA established retroactive Medicare Part A entitlement for a member of a buy-in coverage group, the state must review the individual's eligibility for Part B buy-in over the retroactive period. Under section 1843(d)(2) of the Act and the current version of § 407.47(a), states must

²⁵ When individuals file for disability benefits, SSA determines eligibility for both SSDI and supplemental security income (SSI). The same disability requirements apply to both programs, but other requirements differ. As a result, some individuals receive an SSI award while their SSDI claim or appeal is pending.

²⁶ Individuals who are entitled to premium-free Part A are also eligible to enroll in Medicare Part B under § 407.10(a)(1).

pay Medicare Part B premiums for individuals beginning with the start of the buy-in coverage period. The buy-in coverage period begins with the first month a Medicaid beneficiary is enrolled in Medicaid and qualifies for Medicare, with no limit on retroactivity.²⁷ Therefore, states are retroactively liable for Medicare premiums back to the first month such individuals are determined eligible for Medicare, even in instances involving lengthy delays in Medicare determinations that result in effective dates far in the past.

The following two examples illustrate how retroactive Part A Medicare entitlement for buy-in coverage group members currently affects state liability for retroactive Part B premiums.

Example 1 – Individual is receiving SSI and is enrolled in Medicaid under § 435.120

(“Individuals receiving SSI”) or *meets the eligibility requirements under § 435.121* (“Individuals in states using more restrictive requirements for Medicaid than the SSI requirements”²⁸) and is retroactively entitled to Part A.

- A 55-year-old individual applies for disability-related benefits at SSA in January 2014. SSA determines that the individual is eligible for SSI effective February 2014, and the individual is enrolled in Medicaid and SSI in the same month. (As discussed further in section II.D.5. of this preamble, all states include SSI-related individuals in their buy-in coverage group.) As noted previously, SSA will concurrently determine SSI and SSDI eligibility for an individual who files

²⁷ For individuals enrolled in Medicaid eligibility groups related to cash assistance and QMB, SLMB and QI, § 407.47(b) and (c) specify that the buy-in coverage period begins the later of the *first month* the individual is a member of a buy-in coverage group (that is, the effective date of the individual’s underlying coverage) and eligibility for Part B, or the effective date of the buy-in agreement or modification that includes the buy-in coverage group to which the individual belongs. However, for individuals enrolled in one of the other Medicaid eligibility groups, § 407.47(c) states that the buy-in coverage period starts the later of the *second month* the individual meets the requirements for both eligibility in the buy-in coverage group and Medicare Part B, or the effective date of the buy-in agreement or modification that includes the buy-in coverage group to which the individual belongs.

²⁸ States that have elected the authority provided under section 1902(f) of the Act to apply financial eligibility methodologies more restrictive than SSI’s must provide Medicaid eligibility to certain low-income individuals who seek Medicaid eligibility on the basis of being 65 years of age or older or having blindness or disability.

a disability-related claim. While the disability evaluation is the same for both programs, other programmatic differences result on occasion in some individuals receiving favorable SSI determinations while their SSDI claims are pending.²⁹

- In January 2019, SSA determines the individual to be entitled to SSDI, dating back to January 2013 (one year prior to the disability-related application). The individual's entitlement to Medicare Part A is therefore effective in January 2015. The individual would also be eligible to enroll in Medicare Part B in the same month.

- Because the individual was enrolled in a Medicaid eligibility group that was (and remains) included in the state's buy-in agreement at the point at which the individual became eligible for Part B, and the individual maintained enrollment in the eligibility group, the state Medicaid agency is liable for the individual's Part B premiums effective January 2015 (that is, 48 months of retroactive Part B premium liability).

Example 2 – Individual who is enrolled in Medicaid under § 435.119 (“Coverage for individuals age 19 or older and under 65 at or below 133 percent of the federal poverty level (FPL),” or the “adult group”) is retroactively entitled to Part A.

- A 55-year-old individual applies for disability-related benefits at SSA in January 2014. The individual simultaneously applies for Medicaid. The state determines the individual eligible for the adult group and enrolls him/her in it effective February 2014. The individual's Medicaid eligibility group, the adult group, is included in the state buy-in agreement. (As discussed further in section II.D.5. of this preamble, some states include all Medicaid eligibility groups in their state buy-in coverage group, which means that all eligibility groups added to a state's plan,

²⁹A notable difference in criteria between the two programs is that individuals can seek SSDI payments for up to 12 months before the date of application under § 404.622 of chapter 20, whereas individuals can obtain SSI payments no earlier than the first month after they applied for benefits under § 416.335 of chapter 20.

including ones the state adopted after the state's buy-in election, are included in the buy-in coverage group.)

- In January 2019, SSA determines that the individual is entitled to SSDI, dating back to January 2013 (1 year prior to the disability-related application). The individual's entitlement to Medicare Part A is therefore effective in January 2015. The individual would also be eligible to enroll in Medicare Part B in the same month.

- The state is liable for Part B premiums effective January 2015, the first month the individual is a member of buy-in coverage group and eligible for Part B (that is, 48 months of retroactive Part B premium liability).³⁰

A second implication for states when Medicare enrollment is established retroactively for Medicaid beneficiaries is that the state must determine if it has already paid a Medicaid claim for the individual, because Medicare is the primary payer for dually eligible beneficiaries when services are covered by both programs. In this situation, under section 1902(a)(25)(B) of the Act and § 433.139(d), the state must seek to recoup Medicaid payments to providers for any Medicare-covered services during the period of retroactive Medicare coverage, unless the state determines it is not cost-effective to do so. If Medicaid recoups funds paid to a provider, the provider may bill Medicare, which may require the provider to obtain an exception to Medicare's 1-year timely filing requirement as described in CMS guidance published in Pub. 100-04, Medicare Claims Processing Manual, Chapter 1, Section 70.7.3.³¹ However, the greater the

³⁰ Individuals eligible for Medicare are not eligible for coverage under the adult group under § 435.119. A state must redetermine prospective eligibility for adult group beneficiaries under § 435.916(d) when they become eligible for Medicare. However, an adult group individual who is retroactively entitled to Part A would not in this example have his or her eligibility group retroactively adjusted, and, assuming the state includes all Medicaid eligibility groups in its buy-in agreement, the state would have to enroll this individual in Part B.

³¹ Available on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf>

length of time from the date of service, the more labor-intensive and administratively burdensome it is for the state to recoup Medicaid payments from providers, for the provider to submit a claim to Medicare, and for Medicare to process it.

Retroactive Medicare determinations have also resulted from operational and systems problems preventing the federal government from issuing timely SSDI awards to SSI beneficiaries. Over the past 20 years, SSA has initiated efforts to retroactively enroll SSI recipients in SSDI and Medicare (known as the Special Disability Workload (SDW)) – dating as far back as the 1970s – to remedy operational and systems shortcomings that prevented SSA from originally screening individuals entitled to SSI for disability insurance benefits. SSI beneficiaries who qualify for Medicaid are buy-in coverage group members in all states.³² Under section 1843(d)(2) of the Act, and the current version of § 407.47(g), states technically became liable for retroactive Part B premiums for such beneficiaries going many years back, starting the first month SSA retroactively established Part A entitlement, with no limit on this retroactivity.³³ In 2009, a federal district court ruled that it was not reasonable to require retroactive Part B premium payments by states for long past periods for which the state could not get the benefit of the retroactively determined Medicare eligibility that would be covered by these premium

³² In most states, individuals receiving or who are deemed to be receiving SSI are mandatorily eligible for Medicaid under various groups described in 42 CFR part 435, Subpart B. A minority of states have elected the authority described in section 1902(f) of the Act to apply financial eligibility methodologies more restrictive than SSI's ("209(b)" states, named after the section of the Social Security Act Amendments of 1972, Pub. L. No. 92-603, that authorized the more restrictive methodology). In 209(b) states, individuals receiving or who are deemed to be receiving SSI are not mandatorily eligible for Medicaid, but 209(b) states must afford them certain favorable treatment (for example, states disregard SSI benefits and incurred medical expenses in determining eligibility for SSI beneficiaries; see 42 CFR 435.121(f)).

³³ In states with 1634 agreements ("1634 states"), SSA automatically qualifies individuals entitled to SSI for Medicaid and, once they qualify for Medicare, CMS automatically enrolls those individuals in Part B buy-in. In such states, the retroactive disability and Medicare determinations for the SDW individuals resulted in CMS billing for retroactive Part B premiums going back several years. States without 1634 agreements also owed Part B premiums for the individuals enrolled in SSI and Medicaid during past period, but CMS only billed the state after the state requested buy-in for these individuals.

payments and the state had already incurred the costs of coverage under Medicaid (*NY State v. Sebelius* (N.D. NY, June 22, 2009)). In response to this ruling, CMS implemented a policy under which it does not impose an obligation on states to make retroactive Part B premium payments when SSA operational and systems errors cause lengthy delays in SSDI awards and Medicare eligibility determinations for full-benefit Medicaid beneficiaries and the state cannot obtain the benefit of the Medicare coverage associated with the Part B premium payments the state would otherwise be obligated to make. In addition, CMS currently allows states to request relief on a case-by-case basis from retroactive premiums for periods involving lengthy delays in Medicare determinations to the extent that such delays cover periods for which the state asserts it is too late to benefit from Medicare coverage. CMS considers the potential for beneficiary harm and the state's recoupment policy (that is, time limits on state actions to recoup Medicaid payments from providers) as factors in assessing these state requests. We believe rulemaking is warranted to ensure that the regulations reflect a clear and consistent policy, transparent to all states, on how CMS is addressing the equitable concerns addressed in the previously discussed court decision and subsequent CMS policy implementing it.

Based on our analysis discussed in this section of this rule of when a retroactive period would become so long that the burdens of retroactively processing claims outweigh the benefits of leveraging retroactive Medicare coverage, we propose to add a new paragraph (f)(1) at § 407.47 to establish a general rule under which state liability for retroactive Medicare Part B premiums for full-benefit³⁴ Medicaid beneficiaries under a buy-in agreement would be limited to a period no greater than 36 months prior to the date of the Medicare enrollment determination

³⁴ “Full-benefit” Medicaid coverage, in the context of individuals who are considered “dually” eligible, generally refers to the package of services, beyond coverage for Medicare premiums and cost-sharing, that certain individuals are entitled to under § 440.210 and § 440.330.

(that is, January 2016 in examples 1 and 2). We believe that this proposed revision conceptually aligns with the 2009 court decision limiting state liability for retroactive Medicare Part B premiums for full-benefit Medicaid beneficiaries.

Our proposal would reduce administrative burden on providers for beneficiaries with Medicare determinations more than 36 months in the past, by relieving providers of Medicaid recoupment activities states may find cost-effective to pursue and the need, therefore, to resubmit the claim to Medicare. We estimate that approximately 700 Medicaid beneficiaries per month become retroactively eligible for Medicare for a period of greater than 36 months. It would not create beneficiary liability since Medicaid would have covered any medical costs the beneficiary incurred, and absent state buy-in, the individual would not be enrolled in Part B and, therefore, would not owe any premiums for periods greater than 36 months in the past. We believe that adopting a defined time limit for retroactive Part B premium liability for full-benefit Medicaid beneficiaries reduces burden and promotes efficiencies, clarity and predictability for providers, states, and CMS and is therefore consistent with the authority under section 1902(a)(4) of the Act for the Secretary to find methods of administration “necessary for proper and efficient administration” of the Medicaid program. We note that our proposal does not negate the Secretary’s continuing authority to grant relief in cases of federal government error under section 1837(h) of the Act.

We also propose a “good cause” exception in proposed paragraph (f)(2). This provision would allow an exception for retroactive periods of more or less than 36 months if a currently unforeseen situation arises in which application of the proposed paragraph (f)(1) would result in harm to a beneficiary. Proposed paragraph (f)(2) would also allow CMS to provide relief to states for periods of less than 36 months if we determine the state cannot benefit from Medicare

and limiting state liability would not result in harm to the beneficiary. We seek comment on our proposal for a good cause exception.

Although, as previously noted, we believe that a 36-month retroactive limit strikes the right balance between payment accuracy and reducing administrative burden, we considered proposing limits on state premium liability for time periods longer or shorter than 36 months, including a range from 24 to 60 months. We propose a 36-month limit for two primary reasons. First, we believe Medicaid Management Information Systems (MMIS) would still have Medicaid claims data for dates of service going back at least 36 months. Although state data retention policies vary, state MMIS must maintain sufficient data for multiple purposes, including claims processing, third party recovery, and program integrity efforts to prevent and detect improper payments of claims submitted by providers. Second, the length of time in our proposal is consistent with section 1902(a)(25)(I)(iv) of the Act, under which states must require health insurers, including Parts C and D plans, to accept claims submitted by the state within a minimum of 3 years from the date of service. We invite comment on our proposed 36-month limit, including how it compares with state Medicaid recoupment time-limits, or on alternative options to balance accuracy and burden.

Our proposal to limit state liability for retroactive Part B premiums applies only when Medicaid beneficiaries receive retroactive SSDI and Medicare eligibility determinations from SSA. We are aware that Medicare entitlement delays can also stem solely from federal buy-in system errors, as opposed to retroactive SSDI and Medicare determinations. Such buy-in enrollment delays can occur if a state submits a valid buy-in request to federal systems, but the federal agencies do not process the buy-in enrollment (that is, enroll the individual in Medicare with the state paying the Part A or B premiums or both) and promptly remedy the error. Under

section 1837(h) of the Act, the Secretary has discretion to grant relief to correct or eliminate the effects of such errors or inaction.

We do not propose to extend the 36-month retroactive limit or good cause exception to such enrollment delays which can affect all members of a state buy-in coverage group, including individuals enrolled in partial-benefit Medicaid. Such individuals may need Parts A or B or both for a past period to cover unpaid medical bills. The existing process for these cases allows the Secretary to consider the conditions of each case, and avoid harm to the beneficiaries.

We also propose modifying § 407.47 to clarify our current requirement that states consider all bases of membership in the buy-in coverage group to determine the start date of buy-in. Under section 1843(d)(2) of the Act and § 407.47(a), the beginning of an individual's buy-in coverage period depends on the type of medical assistance they receive under the Medicaid state plan. For individuals enrolled in Medicaid eligibility groups related to cash assistance, as defined in section II.D.4. of this preamble, and QMB, Specified Low-Income Medicare Beneficiary (SLMB) and Qualifying Individual (QI), § 407.47(b) and (c) require the buy-in coverage period to begin the later of the *first month* the individual is a member of a buy-in coverage group (that is, the effective date of the individual's underlying coverage) and eligible for Part B, or the effective date of the buy-in agreement or modification that includes the buy-in coverage group to which the individual belongs. For individuals enrolled in one of the other Medicaid groups, § 407.47(c) requires that the buy-in coverage period starts the later of the *second month* the individual meets the requirements for both eligibility in the buy-in coverage group and Medicare Part B, or the effective date of the buy-in agreement or modification that includes the buy-in coverage group to which the individual belongs.

However, many individuals who qualify as a QMB or a SLMB also qualify under separate Medicaid eligibility groups. While an individual's separate Medicaid eligibility or SLMB eligibility can be retroactive up to 3 months before the application under § 435.915, QMB eligibility is effective no earlier than the month following the month of the determination of such eligibility under sections 1902(e)(8) and 1905(a) of the Act. Thus, if a state determines that an individual is eligible for the QMB eligibility group and a separate Medicaid eligibility group, the individual may first become designated as a member of the buy-in coverage group corresponding to the non-QMB Medicaid eligibility group under which the individual is determined eligible, based on the effective date of such eligibility before they qualify for the buy-in coverage group corresponding to the QMB eligibility group. To determine the start date of the buy-in coverage period, our proposal clarifies at paragraph (a)(2) that the state must take into account the earlier of the buy-in effective dates for the applicable group.

For example, if a Medicare-eligible individual--

- Applies for Medicaid on January 1 of a particular calendar year;
- Is determined in January to be eligible under the eligibility group described in section 1902(a)(10)(A)(ii)(X) of the Act (relating to individuals who have incomes up to the FPL and are either 65 years old or older or with disabilities, which we consider to be an “other Medicaid eligibility group” under our proposed § 407.42(b)(3)) retroactive to October 1 of the previous calendar year (under § 435.915(a));
- Is determined in January to meet all eligibility requirements for the QMB eligibility group; and
- The individual's state has elected to include all Medicaid beneficiaries eligible for Medicare in its buy-in agreement, then Part B buy-in starts on November 1 of the previous

calendar year (that is, the buy-in start date for “other Medicaid eligibility groups,” which is the second month the individual is eligible for the Medicaid eligibility group and Medicare).

While the individual’s QMB eligibility under the state plan will not become effective until February of the particular calendar year, Part B buy-in starts on November 1 of the previous calendar year, because the individual was eligible in a Medicaid eligibility group that was included in the state’s buy-in coverage group effective in October of the previous calendar year (that is, the buy-in start date for “other Medicaid eligibility groups,” which is the second month the individual is eligible for a buy-in coverage group and Medicare).

We believe that our proposal on the effective date of buy-in coverage for individuals who qualify for the buy-in coverage group upon multiple bases will provide greater transparency and certainty to states and beneficiaries, and address confusion about existing requirements.

3. Technical Changes to Regulations on State Payment of Medicare Premiums

a. Revisions to General Definitions (§ 400.200)

Section 400.200 includes general definitions applicable to chapter IV of Title 42. In this section, we describe our proposed revisions and additions to the Medicare Savings Program definitions in § 400.200.

As explained in section II.D.3.h of this proposed rule, we propose to amend Medicaid regulations to add a new definition of the Medicare Savings Programs and to codify the Qualified Medicare Beneficiary, Specified Low Income Beneficiary, Qualifying Individuals, and Qualified Disabled Working Individual eligibility groups for the first time since their enactment. As such, we propose to replace the existing definitions of QMB and QDWI in § 400.200 with streamlined references to the proposed QMB definition in § 435.123 and the proposed QDWI definition in § 435.126, respectively. We also propose to add definitions for the Medicare

Savings Programs, SLMB, and QI in § 400.200 that reference the corresponding proposals defining the Medicare Savings Programs in § 435.4 and the proposed codification of SLMB in § 435.124 and QI in § 435.125. These proposals in § 400.200--and related proposals in Part 435 would bring the regulations in conformance with existing statute and policy and promote consistency and clarity for states.

b. Revisions to Individual Enrollment (§ 406.21)

Paragraph (a) of § 406.21 describes basic limitations on the timing of enrollment in Medicare Part A, in which an individual eligible for Part A may only enroll during his or her IEP, a GEP, an SEP, or, for HMO/CMP enrollees, a transfer enrollment period, as set forth in paragraphs (b) through (f). We propose to modify paragraph (a) to specify that such timing limitations do not apply to individuals enrolling in Part A through a buy-in agreement, as defined in § 407.40. The proposal would codify long-standing policy that QMB-eligible individuals may enroll in Part A at any time of year, without regard to the enrollment periods currently specified in paragraph (a). We propose this change to improve the readability and technical accuracy of the regulation text. We do not believe our proposed update to the regulation text would create any meaningful change in existing CMS policy.

c. Revisions to Enrollment under State Buy-in (§ 406.26)

Section 406.26 describes enrollment in Medicare Part A through the buy-in process. We propose to add a new paragraph (a)(3) to codify long-standing policy against discrimination in the enrollment process. Proposed paragraph (a)(3) would specify that states with a buy-in agreement in effect must enroll any applicant who meets the eligibility requirements for the QMB eligibility group, with the state paying the premiums on the individual's behalf. This proposal, consistent with current policy, prohibits states from applying a cost-effectiveness test

to choose which individuals to enroll in QMB. For instance, states cannot restrict QMB eligibility to those individuals for whom paying the Medicare premium would cost less than covering them through Medicaid alone.

We also propose a revision to paragraph (b)(2) because the current language has proven to be a source of confusion in our interactions with states and other stakeholders. The current paragraph (b) establishes that coverage under buy-in begins with the latest of: (1) the third month following the month in which the agreement modification covering QMBs is affected, (2) the first month in which the individual is entitled to premium hospital insurance under § 406.20(b) and has QMB status, or (3) the date specified in the agreement modification. We propose amending paragraph (b)(2) to clarify that, under a buy-in agreement, as defined in § 407.40, QMB-eligible individuals can enroll in premium hospital insurance (that is, Premium Part A) at any time of the year, without regard to Medicare enrollment periods. This proposal would codify long-standing policy. (The ability to enroll without regard to Medicare enrollment periods was discussed in the rulemaking for § 406.26 in the August 1991 final rule.)

d. Revisions to Enrollment under a State Buy-in Agreement (§ 407.40)

We propose a series of revisions to § 407.40 to reflect statutory updates and codify agency practices related to buy-in agreements.

Section 407.40(a) describes pertinent legislative history on the state buy-in agreements. We propose to add new paragraphs (a)(6) through (a)(9) to cover other statutory changes since § 407.40 was last updated in 1991.

- Proposed paragraph (a)(6) references the establishment of the SLMB eligibility group, as of January 1993, through the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508).

- Proposed paragraph (a)(7) references the establishment of the QI eligibility group, effective January 1998 through the Balanced Budget Act of 1997 (BBA, P.L. 105-33).

- Proposed paragraph (a)(8) references changes to the federal resource standard for QMB, SLMB, and QI to align with those under the Part D program in the Medicare

Improvements for Patients and Providers Act of 2008 (P.L. 110-275) effective January 2010.

This law also required SSA to transfer information from a low-income subsidy (LIS) application to the state Medicaid agency, requiring the agency to use the information to initiate an MSP application.

- Proposed paragraph (a)(9) references the permanent extension of the QI eligibility group through the Medicare Access and CHIP Reauthorization Act (P.L. 114-10) effective April 16, 2015.

- Proposed (a)(10) references the expansion of QMB, SLMB and QI under section 402 of CAA, 2021 (P.L. 116-260) to cover individuals who are enrolled in the Part B-ID benefit.

Paragraph (b) defines terms related to buy-in agreements. Currently, paragraph (b) states that the definitions apply as used in this section, unless context indicates otherwise. However, the terms defined are used throughout subpart C and not solely in § 407.40. Therefore, we propose to replace the term “section” with the term “subpart C.”

We also propose the following changes to the definitions in paragraph (b):

- To revise the definition for aid to families with dependent children (AFDC). As further explained in section II.D.3.e. of this proposed rule, the AFDC program is a cash assistance program that is obsolete but still relevant to buy-in, because some Medicaid eligibility groups remain tied to AFDC, as that program existed as of July 16, 1996, prior to its elimination.

- To remove the definition of “Qualified Medicare Beneficiary” because the term is already defined in § 400.200 to prevent confusion stemming the term being defined in two different places in current regulations.
- To revise the definition of state buy-in agreement, as discussed in detail in section II.B. of this proposed rule.
- To add a definition of a “1634 state” to mean a state that has an agreement with SSA, in accordance with section 1634 of the Act, for SSA to determine Medicaid eligibility on behalf of the state for individuals residing in the state whom SSA has determined eligible for SSI. We are proposing to define this term to improve the readability of the regulation text and codify the term as used today.
- To add a definition of buy-in coverage group to mean a coverage group described in section 1843 of the Act that is identified by the state and is composed of multiple Medicaid eligibility groups specified in the buy-in agreement. We are proposing to define this term to improve the readability of the regulation text and codify the term as used today.

Paragraph (c) describes basic rules for enrollment under buy-in agreements. We propose to revise paragraph (c)(1) under § 407.40 to align with proposed new paragraph (a)(3) under § 406.26, which reflects the current prohibition against discrimination in enrollment and streamlined enrollment processes under buy-in. Specifically, proposed § 407.40(c)(1) would clarify that states with buy-in agreements in effect must enroll any individual who is eligible to enroll in Part B under § 407.10 and who is a member of the buy-in coverage group, with the state paying the premiums on the individual’s behalf. States cannot apply a cost-effectiveness test to choose which individuals to enroll in Part B buy-in. For instance, states cannot withhold buy-in from those who are not separately eligible for full-benefit Medicaid coverage. Additionally, we

propose new text to clarify that states initiate buy-in for eligible individuals who are enrolled in the buy-in coverage group at any time of the year, without regard to Medicare enrollment periods. If a member of a buy-in coverage group is already enrolled in either Medicare Part A or B, the state would directly enroll the individual in buy-in and refrain from referring the individual to SSA to apply for Medicare.

We also propose to add new paragraph (c)(4) to reflect that in a 1634 state, CMS will initiate, on behalf of the state, Part B buy-in for individuals receiving SSI. We are proposing to codify this policy to clarify that all states must ensure that buy-in is initiated, as this current policy has been inconsistently applied in some states.

We also propose to add new paragraph (c)(5) to codify a requirement that premiums paid under a buy-in agreement are not subject to increase because of late enrollment or reenrollment.

e. Revisions to Buy-in Coverage Groups Available for Part B (§ 407.42)

Section 407.42 describes the Part B-related buy-in coverage groups authorized under section 1843(b) through (g) of the Act for the 50 states, the District of Columbia, and the Northern Mariana Islands. Each buy-in coverage group in paragraph (a) includes multiple Medicaid eligibility groups that pertain to dually eligible beneficiaries. Current paragraph (a) identifies individuals who receive, or are deemed to receive, SSI or state supplemental program (SSP) benefits (or both), and are categorically eligible under the state's Medicaid plan. Every buy-in coverage group option described in paragraph (b) includes this population, making it a mandatory buy-in population. Paragraph (a) also affords states the option to target in their buy-in population individuals who are receiving or are treated as receiving AFDC as deemed recipients of cash assistance (in addition to individuals receiving or deemed to be receiving SSI or SSP).

Federal law eliminated the AFDC program in 1996 and, with it, the Medicaid eligibility

link to receipt of AFDC.³⁵ Some Medicaid eligibility groups that covered individuals deemed eligible for AFDC are now obsolete, such as the group serving individuals who have lost AFDC due to increased earnings or hours from employment described at 42 CFR 435.112. However, states must treat beneficiaries in two Medicaid eligibility groups as if they are receiving AFDC for the purposes of Medicaid eligibility determinations under section 1902(a)(10)(A)(i) of the Act. First, under section 473(b) of the Act, states must consider individuals who are receiving adoption assistance, foster care, or guardianship care under title IV-E of the Act (“children eligible based on title IV-E”) as deemed recipients of AFDC. Second, section 1931(b)(1)(A) of the Act (relating to Medicaid eligibility for low-income families) requires that states treat individuals eligible under this provision as receiving AFDC.

All states except one have elected the option under current paragraph (a) to cover individuals who are deemed recipients of the former AFDC program as cash assistance recipients for buy-in. CMS guidance has recognized³⁶ children eligible based on Title IV-E as optional deemed cash assistance recipients for buy-in because they are deemed recipients of AFDC. Although we also consider individuals eligible under section 1931 of the Act to be deemed recipients of the former AFDC program, we have not previously identified such individuals as optional deemed cash recipients for the purposes of buy-in.³⁷ As a result, states opting to cover deemed AFDC recipients as cash assistance recipients for buy-in possibly may not be

³⁵ See section 103(a)(1) of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA) (Pub. L. 104-193). The Temporary Assistance for Needy Families (TANF) program replaced AFDC. However, TANF is not linked to Medicaid coverage and is therefore not a Medicaid eligibility group in the buy-in coverage groups.

³⁶ See Pub. 100-24, State Buy-In Manual, Chapter 1, Section 130.H (November 1996) and December 17, 1987 **Federal Register** (56 FR 47929), entitled “Medicaid Program; Relations With Other Agencies, Miscellaneous Medicaid Definitions, Third Party Liability Quality Control, and Limitations on Federal Funds for Abortions.”

³⁷ Prior to the repeal of title IV-A of the Act, most individuals now covered under section 1931 of the Act received Medicaid based on their receipt of AFDC and were thus optional cash assistance recipients for the purposes of buy-in.

considering individuals eligible under section 1931 of the Act to be cash assistance recipients for buy-in. States generally only cover individuals covered under section 1931 of the Act if they have opted to cover all Medicaid eligibility groups, Group 3 described in this section of this rule.³⁸

In this proposed rule, we clarify that individuals eligible under section 1931 of the Act are optional deemed recipients of cash assistances for the purposes of buy-in based on their classification as deemed recipients of AFDC. We propose to preserve the option in current paragraph (a), allowing states to designate all deemed recipients of AFDC (that is, both children eligible based on title IV-E and individuals covered under section 1931 of the Act) as cash assistance recipients with eligibility groups related to SSI/SSP, or to only cover individuals who receive or are deemed to receive SSI/SSP as cash assistance recipients for buy-in.

Further, under § 407.42, states can cover Part B premiums for Medicaid beneficiaries who are not receiving or being treated as receiving cash assistance (SSI/SSP). States that opt to cover more individuals have the option under paragraph (b)(1) to either select a buy-in coverage group that contains all Medicaid eligibility groups under the state plan (that is, all Medicaid beneficiaries), or SSI/SSP-related eligibility groups and other discrete eligibility populations. By selecting Group 2 in paragraph (b)(2), states agree to pay the Part B premiums for QMBs in addition to SSI/SSP-related eligibility groups, as permitted under section 1843(h) of the Act. As mentioned in section B of this preamble, CMS deemed all buy-in agreements to include the payment of Part B premiums for QMBs unless states opted out. No states opted out of including

³⁸ States that do not cover all Medicaid eligibility groups in their Part B buy-in coverage group do not generally pay the Part B premiums for individuals described in section 1931 of the Act unless they are simultaneously enrolled in another Medicaid eligibility group included in the buy-in coverage group (that is, they also qualify for an MSP eligibility group).

QMB in their buy-in agreements.³⁹

However, § 407.42 does not reference SLMB and QI, two additional MSP groups enacted after the publication of the August 1991 final rule and treated like QMB under our current buy-in policy. Section 1843(h)(3) of the Act specifies that the reference to QMB also includes SLMB. While our subregulatory guidance published for states in 1996 treats SLMB like QMB, combining them under the same buy-in coverage group, we have not updated the regulation text at § 407.42 to mirror the statute or current practice.⁴⁰ Section 1843(h) of the Act does not specifically mention QI as a buy-in eligibility group. However, longstanding CMS operational policy on buy-in agreements (that is, the SPA pre-print pages describing coordination of Medicaid with Medicare and Other Insurance) treats QI like QMB and SLMB, linking the three eligibility groups under one buy-in coverage group.

Paragraph (b) describes seven buy-in coverage groups based on a combination of the underlying eligibility groups in paragraph (a). However, the groups are redundant. Streamlining AFDC-related eligibility groups and clarifying that the reference to QMB includes QMB, SLMB and QI, makes Groups 2, 4, and 6 identical (that is, each includes Medicaid eligibility groups related to SSI/SSP and QMB, SLMB and QI) and Groups 3, 5, and 7 identical (that is, each includes eligibility groups related to SSI/SSP).

Section 407.42 has been a source of confusion for states and other stakeholders. We believe that replacing it with a streamlined listing of the buy-in coverage groups, together with their underlying eligibility groups, is more readily understandable for all parties. Therefore, we propose replacing the current framework in § 407.42 with a more succinct framework. First, we

³⁹ The August 1991 final rule (56 FR 38076).

⁴⁰ Pub. 100-24, State Buy-In Manual, Chapter 1, Section 110 (November 1996).

propose replacing the existing regulation text in paragraph (a) with a general requirement that states must select one of the buy-in coverage groups listed in paragraph (b). We then propose modifying the remaining buy-in coverage groups in paragraph (b) together with the eligibility groups they contain.

The modified buy-in coverage groups we propose in paragraph (b) are as follows:

- Group 1: Individuals who are categorically eligible for Medicaid and:
 - ++ Receive or are deemed to receive SSI or SSP, or both; and
 - ++ At state option, individuals described in section 1931 of the Act and children with adoption assistance, foster care, or guardianship care under title IV-E.
- Group 2: All individuals described in Group 1 and three MSP eligibility groups (QMB, SLMB, and QI).
- Group 3: All Medicaid Eligibility Groups: This group includes all individuals eligible for Medicaid.

Our proposal reflects the three buy-in coverage groups that remain after updating and simplifying the eligibility groups. We propose listing them from narrowest to broadest and include headings to reflect the eligibility groups they contain.

Since no states have opted out of including the payment of Part B for QMBs through their buy-in agreements, all state buy-in agreements currently include the proposed groups 2 or 3. However, since states still retain the option to narrow their agreements to include only eligibility groups related to cash assistance in group 1, our proposal preserves that option. In addition, since nearly all states include in their buy-in agreement as cash assistance recipients individuals eligible under section 1931 of the Act and children eligible based on title IV-E under the deemed AFDC eligibility groups in the current § 407.42(a)(4) (that is, the remaining Medicaid eligibility

groups covering individuals treated as recipients of the former AFDC program), we propose maintaining this discrete option. As described in section II.D.4. of this proposed rule, we seek comment on alternatives considered that might be adopted in a final rule based on comments received. The first alternative would consolidate proposed groups one and two, further reducing the number of buy-in coverage groups from three to two, to mirror the current landscape and simplify the regulation. The other alternative would require states to treat all deemed recipients of the former AFDC program (that is, children eligible based on Title IV-E and individuals covered under section 1931 of the Act) as deemed recipients of cash assistance for buy-in to further streamline the regulation.

f. Revisions to Termination of Coverage under a State Buy-in Agreement (§ 407.48)

Section 407.48 describes the process for terminating an individual's coverage under a state buy-in agreement when he/she is determined ineligible by either CMS or the state. States must communicate all disenrollment information through an established data exchange process with CMS. Currently, paragraph (c)(1) indicates that CMS must determine ineligibility or receive a state ineligibility notice by the "25th day..." in order for the termination date to be calculated using that month. However, CMS no longer applies the uniform monthly deadline of the 25th day of the month for states to send CMS buy-in terminations. Instead, CMS has applied the Current Operating Month (COM) schedule, a schedule developed by SSA with varying monthly processing deadlines, to determine CMS' deadline to receive state terminations in a given month. Each quarter, CMS prospectively conveys the upcoming quarterly COM schedule to states. To align the regulation with current agency practice, we propose amending paragraphs (c)(1) and (c)(2) by replacing the reference to the 25th day with a reference to a new paragraph (e). Our proposed new paragraph (e) would require CMS to prospectively convey to states, on a

quarterly basis, a schedule of processing cut-off dates for each calendar month.

Delays in the receipt of buy-in terminations by CMS impacts state and beneficiary liability after individuals lose eligibility for Medicaid and the state buy-in coverage group.⁴¹ As currently described in paragraph (c)(1), CMS must receive a state buy-in termination notice during the second month after the individual loses eligibility in order for CMS to stop charging the state for Part B premiums the first month the individual no longer qualifies. For example, if an individual loses eligibility for Medicaid and buy-in starting June (that is, is eligible through May), CMS must receive the state termination notice by the August COM deadline in order for state liability to end in June (that is, state premium liability continues through May).

However, if delays in data exchange cause the state to send the termination notification for an individual with an effective date that is earlier than the second month before the processing month, under paragraph (c)(2), CMS will adjust the buy-in termination to the second month prior to the month CMS receives the deletion request. For example, state termination requests received in the processing month of September can have an effective termination date of no earlier than July (that is, state premium liability continues through June). If the state requested an effective date prior to July (for example, April), CMS will automatically adjust the effective date of determination to July (that is, state premium liability continues through June). The state remains liable for premiums through the month of June.

⁴¹ Under § 435.916(f), if an individual is determined by the state Medicaid agency to no longer meet the eligibility requirements for the eligibility group in which they are enrolled, the state Medicaid agency must determine whether the individual is eligible for Medicaid on a separate basis before proposing to terminate the individual's Medicaid eligibility. While the state is making that determination, the state must maintain Medicaid coverage, which means that, if the individual's eligibility group is included in the state's buy-in agreement, the state must continue pay for the individual's Part B premiums.

When federal systems eventually process the buy-in termination, SSA begins charging the beneficiary for Part B premiums. Consistent with paragraph (c)(2), SSA can retroactively recoup up to 2 months of premiums from the individual's Social Security check. In practice, after buy-in termination, SSA deducts 3 months at a time to account for 2 months' retroactive premiums plus the current processing month.⁴² We do not propose any changes to this provision in this regulation, but as we discussed in section II.D.4.d.(4). of this proposed rule, we seek comment on possible modifications to limit beneficiary liability.

g. Revisions to Coordination of Medicaid with Medicare Part B (§ 431.625)

Section 431.625(d)(2) describes the populations for which Federal financial participation (FFP) is available in expenditures for Part B premiums. Section 431.625(d)(1) identifies the basic rule, which is that FFP is generally unavailable to states for their coverage of Part B premiums, except where such coverage is provided to individuals receiving money payments under title I, IV-A, X, XIV, XVI, or state supplements under section 1616(a) of the Act (optional state supplements) or as required by section 212 of Pub. L. 93-66 (regarding mandatory state supplements). Section 431.625(d)(2) lists the exceptions to this basis rule; that is, it lists the Medicaid populations not receiving cash assistance on whose behalf states may both cover their Part B premiums and receive FFP for such coverage.

CMS last updated the current list in paragraphs (i) through (x) in the January 11, 1988 **Federal Register** (53 FR 657), entitled "Medicaid Program; Relations With Other Agencies, Miscellaneous Medicaid Definitions, Third Party Liability Quality Control, and Limitations on Federal Funds for Abortions," (hereinafter referred to as the January 1988 final rule), and it does

⁴² Similarly, in cases where an individual opts to be direct billed for premiums, Medicare would bill the individual for up to 2 months' retroactive premiums plus the current month's premium.

not reflect the adoption of several statutory provisions and regulations to implement them, since that time. Additionally, we have not modified (d)(1) to reflect the repeal of title IV-A of the Act. We thus propose updating § 431.625(d)(1) to eliminate the reference to title IV-A. We also propose updating the outdated list of groups in (d)(2) to remove obsolete groups, make technical changes to some remaining groups, and add two additional groups.

Three groups in the current § 431.625(d)(2) are obsolete, and we propose to remove them from the regulation:

- Paragraph (i): AFDC families eligible for continued Medicaid coverage despite increased income from employment. Although the implementing regulations at §§ 435.112 and 436.116 still exist, this group is obsolete in practice. The Medicare and CHIP Reauthorization Act of 2015 (Pub. L. 114-10) eliminated the sunset provision for Transitional Medical Assistance under section 1925 of the Act, which provides a more robust extension and supersedes this group. Therefore, this group should have no enrollees.

- Paragraph (vi): Deemed recipients of AFDC who are participants in a work supplementation program or denied AFDC because the payment would be less than \$10. As noted in section II.D.3.e. of this proposed rule, the AFDC program was eliminated in 1996. Section 431.625(d)(2)(ii) cross-references these individuals to § 435.115. However, CMS eliminated the references to the AFDC benefit and section 414(g)-related work supplementation programs from § 435.115 for being obsolete in the November 2016 final rule. (CMS has not modified or eliminated the territory regulation cross-reference, at § 436.114, but it is also obsolete.)

- Paragraph (x): Individuals no longer eligible for the disregard of \$30 or \$30 plus one-third of the remainder, but who, in accordance with section 402(a)(37) of the Act, were deemed

AFDC recipients for a period of 9 to 15 months. Section 103(a)(1) of PRWORA repealed paragraph (a)(37) of section 402, making this deemed status obsolete.

Due to the proposed deletion of obsolete groups, we propose to redesignate paragraphs (ii), (iii), (iv), and (v) as paragraphs (i), (ii), (iii), and (iv), respectively; and paragraphs (vii), (viii), and (ix) as paragraphs (v), (vi), and (vii), respectively. We propose to make the following technical changes to the redesignated paragraphs:

- Redesignated paragraph (i): Delete “435.114” which CMS removed from the regulations in the November 2016 final rule.
- Redesignated paragraph (iii): Add cross-references to §§ 435.145 and 436.114(e), which have both been revised since this list was last updated,⁴³ and modify the description of the group to be consistent with the current description of children with adoption assistance, foster care or guardianship care under title IV-E of the Act.
- Redesignated paragraph (iv): Delete “chapter” and add in its place “subchapter”, for specificity and for consistency with this list.
- Redesignated paragraph (vi): Delete the citation to section 1902(e)(3) of the Act and replace it with a cross-reference to § 435.225, the regulation which implemented section 1902(e)(3) of the Act in November 1990, consistent with other cross-references in this list.
- Redesignated paragraph (vii): Add cross-references to §§ 435.115 and 436.114(f) and (h), both of which CMS revised since last updating the list,⁴⁴ and modify the description of the

⁴³ CMS last modified § 435.145 in the November 2016 final rule and last updated § 436.114(e) in the November 21, 1990 **Federal Register** (55 FR 48601), entitled “Medicaid Program; Eligibility Groups, Coverage, and Conditions of Eligibility; Legislative Changes under OBRA ’87, COBRA, and TEFRA,” (hereinafter referred to as the November 1990 final rule).

⁴⁴ CMS last modified § 435.115 in the November 2016 final rule and last changed § 436.114(f) and (h) in the November 17, 1994 **Federal Register** (59 FR 59372), entitled “Aid to Families with Dependent Children; Extension of Medicaid when Support Collection Results in Termination of Eligibility”.

Medicaid eligibility group to reflect the current description of families with extended Medicaid because of increased collection of spousal support under title IV-D of the Act.

While we propose to eliminate from § 431.625(d)(1) the reference to title IV-A, we believe we must account for the statutory directive that individuals described in section 1931(b) of the Act be treated for purposes of Title XIX of the Act as receiving title IV-A assistance. We therefore propose to add to the proposed redesignated paragraph (iii) individuals who are described in section 1931(b) of the Act.

The current § 431.625(d)(2) list of Medicaid eligibility groups also does not reflect the enactment of the MSPs for which the states receive FFP for coverage of premiums or cost sharing or both. Following the redesignated paragraph (d)(2)(vii), we propose adding a new paragraph (viii) to include the QMB, SLMB, and QI eligibility groups, as proposed to be defined in § 400.200, to the eligibility groups for which FFP is available. This proposed addition of paragraph (viii) would codify long-standing policy and bring the regulation in alignment with sections 1902(a)(10)(E) and 1905(p)(3) of the Act, which authorize FFP for the state payment of Medicare Part B premiums for the MSPs.

In addition, we propose a new paragraph (d)(2)(ix) to clarify that states receive FFP for Part B payments for adult children with disabilities described in section 1634(c) of the Act.

Finally, we are taking this opportunity to make a technical correction in § 431.625(d)(3) to update a cross-reference in the third sentence that is now inaccurate, changing “435.914” to “435.915”.

The availability of FFP for state expenditures for dually eligible individuals may affect state decisions regarding the breadth of its Part B buy-in coverage group. Under our proposed § 407.42(b), states can select a buy-in coverage group that only includes Medicaid eligibility

groups related to cash assistance but have the option to select a buy-in coverage group with additional populations (that is, states can choose to cover QMB, SLMB, and QI in addition to Medicaid eligibility groups related to cash assistance or can choose to cover all Medicaid eligibility groups). Including these three MSP eligibility groups in the buy-in coverage group makes it easier for states to meet their obligation to cover Part B premiums for these groups under sections 1902(a)(10)(E) and 1905 (p)(3)(A) of the Act. These sections of the Act and our proposed revisions to § 431.625 allow states to obtain FFP not only for Medicare Part B premiums for Medicaid eligibility groups related to cash assistance but for QMB, SLMB, and QI too.

Although states cannot obtain FFP for Part B premiums for other Medicaid eligibility groups, paying the premiums for these individuals under buy-in helps states maximize federal funding for health care services. First, under section 1905(a)(29)(B) of the Act and § 431.625(d)(3), states cannot obtain FFP for state Medicaid expenditures that could have been paid for under Medicare Part B if the person had been enrolled in Part B. This means, for example, that if a Medicare-eligible individual is enrolled in Medicaid and requires outpatient care, the state Medicaid agency will not receive FFP for Medicaid payments to the individual's outpatient care providers if the individual is not enrolled in Medicare. In addition, under CMS policy, states can require Medicaid applicants and beneficiaries to apply for Medicare as a condition of eligibility, provided that the state pays any Medicare cost-sharing or premiums the individual incurs. If the state does not pay the Part B premiums for a Medicaid beneficiary and he/she does not enroll in Part B, we do not consider Medicare Part B to be a liable third party under part 433 subpart D and, therefore, the state must cover the items and services in accordance with its state Medicaid plan. Thus, it usually is cost-effective for a state to choose to

include additional eligibility groups in its Part B buy-in agreement and pay for the premium, even if no FFP is available for that premium payment, rather than forfeit Medicare coverage or FFP for all services covered that could have been paid for by Medicare Part B.

h. The Medicare Savings Programs (§§ 435.4, and 435.123 through 435.126)

In accordance with section 1902(a)(10)(E) of the Act, states must provide medical assistance to certain low-income Medicare beneficiaries. The eligibility groups described in section 1902(a)(10)(E) of the Act comprise what are generally referred to as the “Medicare Savings Programs.” The four eligibility groups in the Medicare Savings Programs are:

- The Qualified Medicare Beneficiary (QMB) eligibility group, enacted by section 301(e)(1) of the Medicare Catastrophic Coverage Act of 1988 Pub. L. 100-360 and effective January 1989. As described in section 1905(p)(1) of the Act (as amended by section 402 of the CAA), eligibility in this group is available to individuals entitled to Medicare Part A or, on or after January 1, 2023, enrolled in the Part B-ID benefit, and whose income does not exceed 100 percent of the FPL and whose resources do not exceed the standard described in section 1860D-14(a)(3) of the Act, relating to the Medicare Part D full-benefit subsidy. The medical assistance available to the QMB eligibility group is coverage for Medicare Part A and B premiums and cost-sharing, as described in 1905(p)(3) of the Act, including deductibles, coinsurance and copayments.

- The Specified Low-Income Beneficiary (SLMB) eligibility group, enacted by section 4501 of the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508) and effective January 1993. Under section 1902(a)(10)(E)(iii) of the Act (as amended by section 402 of the CAA), eligibility in this group is available to individuals who would otherwise be eligible in the QMB

eligibility group except that their income exceeds 100 percent of the FPL and is below 120 percent of the FPL. The medical assistance for SLMBs is coverage for Part B premiums.

- The Qualifying Individuals (QI) eligibility group, enacted by section 4732 of the Balanced Budget Act (BBA) of 1997 (P.L. 105-33) and effective January 1998. Under section 1902(a)(10)(E)(iv) of the Act (as amended by section 402 of the CAA), eligibility in this group is available to individuals who would otherwise be eligible in the QMB eligibility group except that their income is at least 120 percent of the federal poverty level and below 135 percent of the federal poverty level. The medical assistance for QIs is coverage of Part B premiums.

- The Qualified Disabled Working Individuals (QDWI) eligibility group, enacted by section 6408 of the Omnibus Budget Reconciliation Act (OBRA) 1989 (Pub. L. 101-239) and effective July 1990. As described in section 1905(s) of the Act, eligibility in this group is available to individuals entitled to Medicare Part A under section 1818A of the Act, whose income does not exceed 200 percent of the federal poverty level, and whose resources do not exceed twice the maximum amount permitted under the SSI program. The medical assistance for QDWIs is coverage for Part A premiums.

The Medicare Savings Programs include four mandatory eligibility groups. Section 1905(p)(1) and 1902(a)(10)(E) of the Act (for the QMB, SLMB, and QI eligibility groups) and 1905(s)(2) and (3) of the Act (for the QDWI eligibility group) require that states use SSI income and resource methodologies to determine financial eligibility. CMS has not codified the Medicare Savings Programs in part 435 of this chapter. We propose to include the Medicare Saving Programs in the listing in subpart B of part 435 and to add a definition of the Medicare Savings Programs in § 435.4.

We believe that our proposals in part 435—together with our proposals in § 400.200—would ensure consistency and transparency in our regulations and avoid confusion for stakeholders. In addition, as described in sections I.B. and II.B. of this proposed rule, section 402 of the CAA amends the Medicare Savings Programs under sections 1905(a)(1)(A) and 1902(a)(10)(E) of the Act to pay some or all of the costs of the new immunosuppressive drug coverage for certain low-income individuals who are enrolled in such drug coverage. We believe that our proposals to codify the Medicare Savings Programs in the Medicaid regulations provide the necessary foundation upon which to codify the expansion of Medicare Savings Program eligibility in section 402 of the CAA.

First, we propose to add to § 435.4 a definition of the Medicare Savings Programs consistent with section 113 of MIPPA, which defines the term Medicare Savings Programs to include the QMB, SLMB, QI, and QDWI eligibility groups. Second, we propose to add new § 435.123 to codify the QMB eligibility group under sections 1902(a)(10)(E)(i) and 1905(p)(1) of the Act. Proposed § 435.123(b)(1) reflects that under section 1905(p)(1)(A) of the Act, QMBs must be either entitled to premium-free Part A coverage that is applicable to the vast majority of Medicare beneficiaries or entitled to Part A coverage for individuals age 65 and over who must pay a premium to enroll in Part A. QMB status is not available to individuals entitled to Part A solely based on eligibility to enroll as a Qualified Disabled and Working Individual (QDWI) as specified in section 1905(p)(1)(A) of the Act. In addition, proposed § 435.123(b)(1) incorporates the expansion of MSP eligibility under section 402 of the CAA to cover individuals who are enrolled in Medicare Part B for coverage of immunosuppressive drugs.

Proposed § 435.123 (b)(2) and (b)(3) describe the income and resource limits for the QMB eligibility group identified previously. Further, proposed § 435.123(b)(2) and (b)(3)

reflect that under section 1902(r)(2) of the Act and § 435.601(d)(1)(i), states can choose to disregard certain types of income and resources in a manner that is less restrictive than SSI methodologies. According to the Medicaid and CHIP Payment and Access Commission (MACPAC), as of February 2020, 14 states and the District of Columbia had adopted income or resources standards or both that are more generous than SSI's for the QMB eligibility group as well as two other MSPs, the SLMB and QI eligibility groups.⁴⁵

We are also proposing to include proposed (b)(2)(i) and (b)(2)(ii) to codify in regulation the statutory requirements pertaining to the treatment of a cost of living adjustment (COLA) for Social Security retirement, survivors, and disability benefits in determining eligibility for the QMB, SLMB, and QI eligibility groups. Under section 1905(p)(2)(D) of the Act, income attributable to a Social Security COLA is not countable as income for QMB, SLMB, or QI eligibility purposes during a “transition month,” which the statute defines as each month through the end of the month following the month the U.S. Department of Health and Human Services (HHS) publishes the revised official poverty level in the **Federal Register**. For example, in a year in which an individual receives a Social Security income-related COLA adjustment beginning in January, and HHS publishes the updated federal poverty levels in February, the COLA is not countable as income in determining eligibility for the QMB, SLMB and QI eligibility groups until April.

⁴⁵ According to the Medicaid and CHIP Payment and Access Commission (MACPAC), Alabama, Connecticut, Delaware, District of Columbia, Illinois, Indiana, Louisiana, Maine, Massachusetts, Mississippi, New York, Oregon and Vermont use less restrictive definitions of income and resources than SSI's in February 2020. See Chapter 3: Improving Participation in the Medicare Savings Programs, in MACPAC. (2020, June). Report to Congress on Medicaid and CHIP.. <https://www.macpac.gov/wp-content/uploads/2020/06/June-2020-Report-to-Congress-on-Medicaid-and-CHIP.pdf>, (hereinafter referred to as “Chapter 3 in MACPAC’s June 2020 Report to Congress”). In addition, beginning January 1, 2021, New Mexico adopted less restrictive definitions than SSI for resources.

We are aware of states that have inappropriately moved to terminate eligibility during a transition month by continuing to apply the prior year's poverty levels and failing to disregard the COLA. Such actions are inconsistent with the statute and harmful to beneficiaries. We remind states that state agencies must not wait until CMS notifies them of the new official poverty levels before adjusting their eligibility standards. They must adjust their eligibility standards to reflect the updated poverty level as soon as the Secretary publishes the new poverty level figures in the **Federal Register**. We are proposing to codify these requirements in regulation.

Proposed § 435.123(c)(1) reflects that Medicaid covers the Medicare Parts A and B premiums and cost-sharing for individuals entitled to Part A for QMB, and proposed § 435.123(c)(1) (c)(2) reflects that Medicaid covers premiums and cost-sharing for QMBs enrolled in Part B for coverage of immunosuppressive drugs for QMB under section 402 of the CAA.

In addition to the proposed codification for the QMB eligibility group, we propose to add new § 435.124 for the SLMB eligibility group and new § 435.125 for the QI eligibility group described in section 1902(a)(10)(E)(ii) and (iv) of the Act, respectively. Paragraphs (b) and (c) of the proposed SLMB and QI provisions are consistent with the proposed § 435.123 for the QMB eligibility group, with the exception of the different income thresholds that apply to them as compared to the QMB eligibility group, as identified previously. We note that section 1902(a)(10)(E) of the Act sets forth the eligibility criteria for these MSP eligibility groups but does not assign the names SLMB and QI.

Lastly, we propose to add a new § 435.126 for the QDWI eligibility group. Paragraphs (a) through (c) of the proposed QDWI provision reflect that, in accordance with sections

1902(a)(10)(E)(ii) and 1905(s) of the Act, QDWI pays the Part A premiums for individuals under age 65 who become entitled to Part A based on their receipt of SSDI, but who subsequently lose SSDI, and as a result, their Part A entitlement, on the basis of gainful employment. Section 1818(g) of the Act does not permit states to pay the Part A premium for QDWIs under a state buy-in agreement. States pay the Part A premium for QDWIs through the group payer process.

4. Alternative Proposals Considered on Modernizing State Payment of Medicare Premiums

We considered several alternatives to the proposed policies and technical changes as previously described in sections IV.D.1 through 3. of this proposed rule as part of this proposed rulemaking. We describe those alternatives in this section of this rule. In each case, we welcome comments to inform future rulemaking and operational improvements in this area.

a. Part B Buy-in Coverage Groups (§ 407.42(b))

In section II.D. of this preamble, we described our proposal to reduce the number of Part B buy-in coverage groups described at § 407.42(b). We also considered two alternatives that might be adopted in final regulation based on comments received. The first option would further reduce the number of Part B buy-in coverage groups from our proposed three groups to two groups, to reflect current practice among states and simplify the regulatory text. As background, the regulation currently provides states the option to pick from among different buy-in coverage groups. However, since no states have opted out of including the payment of Part B for QMBs, all state buy-in agreements currently include groups 2 or 3 described in proposed paragraphs (b)(2) and (3). Therefore, no states only cover Medicaid eligibility groups related to cash assistance in buy-in coverage group 1 described in proposed paragraph (b)(1). We seek

comment on potentially narrowing the buy-in coverage group options to groups 2 and 3, and might adopt this alternative considered in the final rule based on comments received.

We considered a second set of alternatives on state payment of the Part B premiums for deemed AFDC eligibility groups. As noted previously, the AFDC program was repealed. However, states must still consider certain Medicaid beneficiaries as deemed recipients of AFDC (that is, individuals covered under section 1931 of the Act and children covered under title IV-E for the Act) for the purposes of Medicaid eligibility determinations. All states except one have opted to treat all deemed recipients of the former AFDC program as cash assistance recipients for buy-in. We considered proposing to require all states to include all deemed AFDC eligibility groups as deemed recipients of cash assistance. However, we chose not to propose such a change at this time to consider the broader implications for states and beneficiaries, but we request comments for consideration for the final rule on the operational, fiscal, and beneficiary impacts of such a proposal.

b. Buy-in Programs in the U.S. Territories (§ 407.43)

We considered updating § 407.43, which governs buy-in coverage groups for the four U.S. territories of Puerto Rico, American Samoa, U.S. Virgin Islands, and Guam,⁴⁶ similar to our proposal to streamline and clarify buy-in coverage groups in § 407.42, and might adopt this alternative considered in the final rule based on comments received. However, because there are special considerations in the territories, we chose not to propose changes at this time. For example, unlike the 50 states and DC, federal Medicaid funding is capped for the five U.S. territories (American Samoa, Guam, the Commonwealth of the Northern Mariana Islands (CNMI), Puerto Rico, the U.S. Virgin Islands) under section 1108 of the Act. Additionally,

⁴⁶ The Northern Mariana Islands are governed by § 407.42.

Guam, Puerto Rico, and the U.S. Virgin Islands are not required to cover QMBs under 1905(p)(4)(A) of the Act. American Samoa and the CNMI likewise do not cover QMBs as permitted by waivers under section 1902(j) of the Act.

We seek comments for consideration in the final rule on whether updating the buy-in coverage groups in § 407.43 with a more succinct framework would aid Medicaid agencies in the U.S. territories in administering their buy-in programs and improve beneficiary experiences.

c. Months of Premiums for which SSA may Bill Beneficiaries when Buy-in Ends (§ 407.48(c))

We considered proposing modifications to § 407.48(c) to further limit the number of month of premiums for which SSA may bill beneficiaries when buy-in ends. As background, due to delays in buy-in data exchange between states, CMS, and SSA, states often continue to pay Medicare Part B premiums for beneficiaries after they lose eligibility for Medicaid and buy-in. When federal systems eventually process the buy-in termination, SSA begins charging the beneficiary for Part B premiums, and CMS refunds the state for those same premiums. Since 1972, federal regulations have specified that, after buy-in ends, SSA can retroactively recoup up to 2 months of premiums from the individual's Social Security benefits (any premiums for months further in the past remain the responsibility of the state).⁴⁷ In practice, SSA deducts 3 months of premiums at a time to account for 2 months retroactive premiums plus the current processing month. This can jeopardize the individual's ability to pay for food and rent in the first month, increasing the risks of hunger or eviction. We did not formally propose a change at this time because we need more time to consider how to best structure a proposal that balances beneficiary protections with statutory compliance and fiscal considerations. We welcome comments to inform future rulemaking on this topic.

⁴⁷ This policy is currently codified at § 407.48(c).

d. State Payment of Medicare Premiums when Medicare Benefits are Not Available (§§ 406.26 and 407.40)

We considered revising § 406.26 and § 407.40 to remove premium liability for states in other situations in which Medicare benefits are not available. The 2009 decision in *NY v. Sebelius* enjoined CMS from billing New York during periods of retroactive Medicare eligibility in which the state would not benefit from Medicare (that is, it was too late for Medicare benefits to be provided). We believe that there may be similar situations in which Medicare eligibility can be established but Medicare benefits would not be provided. For example, individuals who are incarcerated or residing overseas may still retain entitlement to Medicare but be ineligible for payment for services because of their status. We request comment on the implications of limiting liability for states because Medicare is unavailable in these two examples or any others, and might adopt this alternative considered in the final rule based on comments received.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 et seq.), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a “collection of information” requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA’s implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.

- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected

public, including automated collection techniques.

Through this rule we are soliciting public comment on each of these issues for the proposed provisions that have collection of information implications.

A. Wage Estimates

To derive average costs for individuals, we used data from the U.S. Bureau of Labor Statistics’ (BLS) May 2021 National Occupational Employment and Wage Estimates for our salary estimates (www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 1 presents BLS’ mean hourly wage, our estimated cost of fringe benefits and overhead, and our adjusted hourly wage.

TABLE 1: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
All Occupations	00-0000	28.01	n/a	n/a

The mean wage under All Occupations applies to a group of respondents that varies widely from working and nonworking individuals and by respondent age, location, years of employment, educational attainment, and other factors. We are not adjusting this figure for fringe benefits and overhead since the individual’s enrollment activities would occur outside the scope of their employment, should they be employed.

B. Proposed Information Collection Requirements (ICRs)

The following topics are listed in the order of their appearance in section II of this preamble.

1. ICRs Regarding Beneficiary Enrollment Simplification (§§ 406.27 and 407.23)

The following proposed changes will be submitted to OMB for review under control number 0938-TBD1 (CMS-10797). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request.

As described in section II.A. of this rule, we are proposing to amend §§ 406.27 and 407.23 to provide special enrollment periods (SEPs) for individuals experiencing an exceptional condition to enroll in Medicare premium Part A and Part B. To utilize these new SEPs, an individual would have to submit an enrollment request via a new enrollment form. The form would be used by individuals who have missed an enrollment period due to an exceptional condition to enroll in Part A and/or Part B (see section II.A. of this preamble for a more detailed discussion).

As part of the PRA process, the proposed form (CMS-10797) will be made available for public review and comment (see section III.D. of this preamble for additional information).

We estimate that it would take an individual approximately 15 minutes (0.25 hr) to complete the form, pull together any required supporting documentation, and submit the completed form to CMS.

Due to the newness of the proposed SEPs, CMS does not have precise data to estimate the number of individuals that may enroll under the new exceptional condition SEPs. However,

we believe that the closest equivalent is using the number of individuals enrolled during the GEP because the SEPs provide an opportunity to enroll outside of the GEP.

TABLE 2: GEP ENROLLMENTS FROM 2016 - 2020

Year	Individuals Enrolling in Premium Part A During the GEP	Individuals Enrolling in Part B During the GEP	Total Part A and B GEP Enrollments
2016	6,546	102,935	109,481
2017	2,021	99,728	101,749
2018	1,819	98,473	100,292
2019	2,223	104,808	107,031
2020	2,221	103,373	105,594
Total	14,830	509,317	524,147
5-Year Average	2,966	101,863	104,829

Based on these data, we estimate that the average number of GEP enrollments per year is 2,966 for premium Part A and 101,863 for Part B (totaling 104,829 annually). We also assume that only a portion of the enrollments would involve an SEP enrollment request since the new SEPs are applicable only for exceptional conditions. Assuming that 30 percent of individuals who normally would have had to wait until the GEP to enroll would now be eligible using an SEP would result in 31,449 (104,829 enrollments x 0.30) SEP requests annually. As such, we estimate an annual ongoing burden of 7,862 hours (31,449 requests x 0.25 hr/ request) at a cost of \$220,214.62 (7,862 hr x \$28.01/hr).

2. ICRs Regarding Extended Months of Coverage of Immunosuppressive Drugs for Kidney Transplant Patients (§§ 407.57, 407.59, 407.62, and 407.65)

With regard to our proposed Part B-ID benefit attestation requirements, the following proposed changes will be submitted to OMB for review under control number 0938-TBD2 (CMS-10798). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's

collection of information request.

With regard to our proposed requirements for termination of the Part B-ID benefit, the following proposed changes will be submitted to OMB for review under control number 0938-0025 (CMS-1763).

Our proposed enrollment reporting requirement will be submitted to OMB for review under control numbers 0938-0958 (CMS-10143) and 0938-0345 (CMS-R-284).

a. Attestations (CMS-10798, OMB 0938-TBD2)

As described in section II.B of this rule, Congress enacted section 402 of the CAA, amending sections 226A, 1836, 1837, 1838, 1839, 1844, 1860D-1, 1902, and 1905 of the Act to provide immunosuppressive drug coverage for certain individuals whose Medicare entitlement based on ESRD would otherwise end 36 months after the month in which they received a successful kidney transplant. We propose as a condition of enrollment, in §§ 407.57 and 407.59 of this rule and as required in section 402 of the CAA, that an individual must attest that (a) they are not enrolled and do not expect to enroll in coverage described in proposed §407.55, and (b) they will notify the Commissioner within 60 days of enrollment in such other coverage.

To facilitate deemed enrollment into the Part B-ID benefit, eligible beneficiaries whose coverage will be terminating 36 months after the month of a successful kidney transplant will be provided information about the Part B-ID benefit, and informed that they can enroll in this coverage by attesting that they do not have other excepted coverage. We plan to include information about the Part B-ID benefit in the pre-termination notice, as discussed in section II.B.2.b. “Determination of Eligibility” of this proposed rule, and include instructions for individuals to enroll in the Part B-ID benefit, including how to provide the required attestation. We, along with SSA believe that a verbal (telephonic) method would be the most efficient

method for a beneficiary to provide the attestation required to enroll in the Part B-ID benefit. It is easily accessible and would avoid potential delays in an individual receiving this vital coverage, as it would not be interrupted or delayed by disruptions in mail or other unforeseen circumstances.

If the individual is not amenable to the verbal attestation, they can visit the website address provided to download a PDF-fillable version of the form to submit to SSA, or call SSA to request a paper form.

The attestation options would also be available for individuals who were previously terminated from Medicare based on ESRD after 36 months, or individuals who are reenrolling into the Part B-ID benefit for coverage of immunosuppressive drugs.

We expect that the population of individuals eligible for the Part B-ID benefit will use all available options (telephonic attestation, completion and submission of website-accessed PDF-fillable forms, and completion of paper forms requested from CMS or SSA) to provide the required attestation to SSA. We expect that each of the options for providing the required attestation will require approximately the same burden. We estimate that individuals attesting telephonically or via a paper or .pdf attestation form would have the same burden of 10 minutes (0.167 hr) per response.

CMS's Office of the Actuary (OACT) expects an average of 767 individuals, whose Medicare entitlement based on ESRD which ended 36-months after the month in which they received a successful kidney transplant, to request enrollment in the Part B-ID benefit from 2023 through 2025. This estimate was provided by CMS actuaries based on historical information provided by SSA on the number of individuals who had prior Medicare Part A coverage and a kidney transplant between 2001 and 2019, and then making downward adjustments to account

for those individuals who are deceased or who are anticipated to have other comprehensive coverage and would not be eligible for the Part B-ID benefit. The overall results of applying these assumptions is that roughly 1,800 individuals would be enrolled in the Part B-ID benefit in 2023, with an estimated growth of 250 enrollees each year thereafter. This would equate to approximately 2,300 individuals enrolling in the Part B-ID benefit from 2023 through 2025, or an annual estimated enrollment of 767 individuals. The burden associated with the Part B-ID benefit is the time required to complete and submit an attestation. We estimate a total annual burden of 128 hours (767 Part B-ID enrollees * 0.167 hr/response) at a cost of \$3,585 (128 hr * \$28.01/hr).

As part of the PRA process, the proposed form and telephonic script (CMS-10798) will be made available for public review and comment (see section III.D. of this preamble for additional information).

b. Termination of the Part B-ID Benefit (CMS-1763, OMB 0938-0025)

As proposed in § 407.62 of this rule, individuals can voluntarily terminate their Part B-ID benefit at any time by notifying SSA. Primarily, we are proposing that an individual would contact SSA to request termination, either telephonically, or by visiting an SSA field office. We are also proposing that if an individual is not amenable to contacting SSA to terminate their Part B-ID benefit, they can access the CMS or SSA website and print, sign and mail the form to SSA, or call SSA to request a paper form to submit their request. We expect that all available options (SSA contact, completion and submission of website-accessed form, and completion of paper form requested from CMS or SSA) to request a termination from the Part B-ID benefit will be used by beneficiaries. We expect that each of the options for requesting a termination from the

Part B-ID benefit will require approximately the same burden, namely 10 minutes (0.167 hr) per response.

Currently, individuals who are requesting termination of premium Hospital Insurance (Part A) or termination of Supplementary Medical Insurance (Part B) or both can complete the CMS-1763 form. While we are proposing to revise the form to include termination of the Part B-ID benefit, we are not proposing to change our currently approved per response time estimate of 10 minutes (0.167 hours) per response.

We have limited means of estimating how many individuals will opt to terminate their Part B-ID benefit as this immunosuppressive drug benefit is yet to be implemented – the statutory effective date is January 1, 2023. However, for estimation purposes, we assume an average of 10 percent of the individuals enrolled in the Part B-ID benefit will voluntarily disenroll. As discussed in section III.B.2.a. of this proposed rule, OACT estimates that approximately 767 eligible individuals will enroll in the Part B-ID benefit annually from 2023-2025, we estimate that 77 of these individuals ($767 \text{ eligible individuals} \times 0.10$) will voluntarily terminate their Part B-ID benefit. This would not include individuals who are involuntarily terminated from the Part B-ID benefit because CMS or SSA determined that they had other coverage that made them ineligible for the Part B-ID benefit, or because they failed to pay the required premium. Also excluded from this number are individuals who will obtain Medicare coverage based on age, disability, or ESRD status, and therefore, will not remain enrolled in the Part B-ID benefit, and individuals who die. Our methodology was to estimate the total Part B terminations as a percent of total Part B enrollments annually from 2019-2021 (about 3

percent).⁴⁸ We then assumed that the Part B-ID benefit terminations would be more frequent, as we anticipate that individuals may explore options available for more comprehensive coverage, given an individual's other post-transplant associated expenses. Therefore, we increased that percentage to 10 percent. We then used OACT's growth estimate of 767 enrollments annually between 2023 and 2025 to estimate that 10 percent of those enrollments, or approximately 77 annually, would terminate their Part B-ID benefit voluntarily.

Based on voluntary terminations of the Part B-ID benefit only, by the methods described previously, we expect a total annual burden of 13 hours (77 requests to terminate the Part B-ID benefit x 0.167 hr) at a cost of \$364 (13 hr x \$28.01/hr) per year. Although, we have limited means to determine the actual number of individuals who will terminate their coverage; however, as we implement this benefit, we will have data to better adjust (if/when needed) our burden estimates in the future.

As part of the PRA process, the proposed revisions to form CMS-1763 will be made available for public review and comment (see section III.D. of this preamble for additional information).

c. Reporting of MSP Part B-ID Benefit Enrollment Information (CMS-10143, OMB 0938-0958) and (CMS-R-284, OMB 0938-0345)

As described in section II.B. of this rule, under section 402(f) of the CAA, we are proposing to modify three Medicare Savings Programs (MSP) eligibility groups (Qualified Medicare Beneficiary (QMB), Specified Low-Income Medicare Beneficiary (SMLB) and Qualifying Individual (QI)) to pay premiums and, if applicable, cost sharing for low-income

⁴⁸ Data source: ELMO, 12/3/2021.

beneficiaries enrolled in Part B-ID (MSP Part B-ID). Under the MSP Part B-ID benefit, states will pay the Part B-ID benefit premiums and cost sharing for QMBs, and Part B-ID benefit premiums for SLMBs and QIs.

Once states enroll individuals in a MSP Part B-ID benefit, states will need to report the enrollment information to CMS. We anticipate enrollment in a MSP Part B-ID benefit mainly occurring in the 12 states that, as of December 2021, have elected to not expand Medicaid eligibility to adults with income up to 138 percent of the FPL (“non-expansion states”). Those 12 states are Alabama, Florida, Georgia, Kansas, Mississippi, North Carolina, South Carolina, South Dakota, Tennessee, Texas, Wisconsin and Wyoming.

Given that the income requirements for QMB, SLMB, and QI are all below 138 percent of the FPL, individuals losing MSP coverage in one of those eligibility groups due to loss of entitlement for ESRD Medicare in expansion states would be eligible for Medicaid in the adult group under § 435.119. Because the adult group is a full-benefit Medicaid eligibility group providing immunosuppressive drug coverage, individuals who enroll in the adult group would not be eligible for the Part B-ID benefit. Although some expansion states may use income disregards to boost MSP income limits above the income threshold for the adult group, these individuals would then be eligible for Advanced Payment of Tax Credits (APTCs) and Cost Sharing Reductions (CSRs) to purchase health insurance through a Qualified Health Provider (QHP) in the Exchange established by the Affordable Care Act and implemented at 45 CFR part 155. As a result, we do not believe these individuals would elect to enroll in a MSP Part B-ID benefit when they are able to enroll in more comprehensive coverage that is subsidized in the Exchange. Similarly, in non-expansion states, we do not expect anyone who can qualify for subsidized insurance in the Exchange to enroll in a MSP Part B-ID benefit.

As such, we believe individuals who fall into the coverage gap in the non-expansion states – that is individuals whose income prevents them from receiving Medicaid coverage, but is too low to qualify for APTC or CSR in the Exchange – will enroll in a MSP Part B-ID benefit. In the MSP eligibility groups, the only individuals who would fall into this category are QMBs. We reviewed internal data from 2021 to determine how many individuals were enrolled in MSPs, had Medicare entitlement based on ESRD, and were 36 months post-transplant. Applying this data to an annual timeframe would yield 276 individuals enrolled as QMB-only, all in non-expansion states. However, because not everyone will necessarily enroll, based on our actuaries' estimate, we anticipate only 250 individuals per year enrolling in the Part B-ID benefit, all of whom will enroll through the QMB Part B-ID benefit. Because we anticipate all of these individuals will initially be enrolled in MSPs and simply converting over to a MSP Part B-ID benefit when they lose Medicare entitlement based on ESRD and then enrolling in the Part B-ID benefit, we do anticipate that there will be any new or revised burden for these enrollees to apply for a MSP Part B-ID benefit other than the initial enrollment in the Part B-ID benefit. Rather, the burden for enrolling these individuals will fall on the state when it is performing a redetermination of Medicaid eligibility. As described in section II.B of this rule, when an individual loses Medicaid eligibility, a state must already perform a redetermination under all categories of eligibility per § 435.916(f)(1). As such, we do not anticipate any new or revised burden on states enrolling these individuals either.

We also believe there will not be any new or revised reporting burden on states for the MSP Part B-ID benefit individuals because they will receive coverage under existing MSP eligibility groups (that is, QMB, SLMB and QI). States already submit enrollment information for all current MSP enrollees through Medicare Modernization Act (MMA) under control

number 0938-0958 (CMS-10143) and Transformed Medicaid Statistical Information System (T-MSIS) under control number 0938-0345 (CMS-R-284) files, and we do not believe including the new MSP Part B-ID benefit enrollees in the MMA and T-MSIS file submissions to CMS will result in any new burden. For the MMA file, we will inform states to report MSP Part B-ID benefit enrollees using the exact same code as for any other MSP enrollee, but that CMS will determine MSP Part B-ID benefit enrollment by examining both the MSP code and the Medicare enrollment reason code. For the T-MSIS file, we will inform states to report MSP Part B-ID benefit enrollees using the exact same code as for any other MSP enrollee, but to fill in a different value for another field. Because we expect no coding changes to either MMA or T-MSIS files, we do not anticipate that any system changes would be necessary for submitting these files to CMS.

Because we are not anticipating any new reporting requirements or burden as a result of these changes, we will not be making any changes to approved CMS-10143, OMB 0938-0958 or CMS-R-284, OMB 0938-0345.

3. ICRs Regarding Simplifying Regulations Related to Medicare Enrollment Forms (§§ 406.7 and 407.11)

As described in section II.C. of this rule, we are proposing to revise §§ 406.7 and 407.11 to remove all references to specific enrollment forms that are used to apply for entitlement under Medicare Part A and enrollment under Medicare Part B. This is an administrative change that would have no impact on the use or availability of these forms and would not impose or affect any information collection requirements or burden. CMS is proposing to remove references to the following four forms that are currently OMB approved and are still in use under the approved scope:

- Medicare Part A Enrollment Forms (§406.7)

++ CMS-18-F-5 (OMB 0938-0251) - Application for Hospital Insurance Entitlement

++ CMS-43 (OMB 0938-0080) - Application for Health Insurance Benefits under Medicare for Individuals with End Stage Renal Disease (ESRD)

- Medicare Part B Enrollment forms (§407.11)

++ CMS-18-F-5 (OMB 0938-0251) - Application for Hospital Insurance Entitlement

++ CMS-4040 (OMB 0938-0245) - Application for Enrollment in the Supplementary Medical Insurance Program.

++ CMS-40-B (OMB 0938-1230) - Application for Enrollment in Medicare Part B (Medical Insurance)

++ CMS-40-D⁴⁹ - Application for Enrollment in the Supplementary Medical Insurance Program.

++ CMS-40-F⁵⁰ - Application for Medical Insurance

⁴⁹ CMS-40-D was obsoleted 3/2022

⁵⁰ CMS- 40-F was obsoleted in 2008

C. Summary of Annual Burden Estimates for Proposed Changes

TABLE 3: PROPOSED ANNUAL REQUIREMENTS AND BURDEN ESTIMATES

Regulation Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID Number)	Respondents	Total Responses	Burden per Response (hours)	Total Time (hours)	Labor Cost (\$/hr)	Total Cost (\$)
§§ 406.27 and 407.22	0938-TBD1 (CMS-10797)	31,449	31,449	0.25	7,862	28.01	220,215
§ 407.59	0938-TBD2 (CMS-10798)	767	767	0.167	128	28.01	3,585
§ 407.62	0938-0025 (CMS-1763)	77	77	0.167	13	28.01	364
TOTAL		32,293	32,293	Varies	8,003	28.01	224,164

D. Submission of Comments

We have submitted a copy of this rule to OMB for its review of the rule's proposed information collection requirements and burden. The requirements would not be effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections previously discussed, please visit CMS's website at

[https://www.cms.gov/RegulationsandGuidance/Legislation/](https://www.cms.gov/RegulationsandGuidance/Legislation/PaperworkReductionActof1995/PRAListing.html)

[PaperworkReductionActof1995/PRAListing.html](https://www.cms.gov/RegulationsandGuidance/Legislation/PaperworkReductionActof1995/PRAListing.html), or call the Reports Clearance Office at (410) 786-1326.

We invite public comments on the proposed information collection requirements and burden. If you wish to comment, please submit your comments electronically as specified in the DATES and ADDRESSES sections of this proposed rule and identify the rule (CMS-4199-P) and where applicable the ICR's CFR citation, CMS ID number, and OMB control number.

IV. Regulatory Impact Analysis

A. Statement of Need

This proposed rule would implement certain Medicare-related provisions of the CAA, as well as propose other enrollment-related changes. Section 120(a)(1) of the CAA revised the entitlement periods for individuals who enroll in Medicare Part B in the last 3 months of their IEP, deemed IEP, or during the GEP, beginning January 1, 2023. Under longstanding Medicare rules, the effective date of entitlement varies depending on whether the individual is enrolling during the IEP or GEP and when an enrollment is made during each specific enrollment period which could cause confusion. The proposed changes should help eliminate this potential

confusion by establishing a straightforward and uniform policy regarding Part A and Part B entitlement start dates.

Section 120 of the CAA also gives the Secretary the authority to establish SEPs for exceptional conditions. Under current rules, individuals are only able to enroll outside of the IEP or GEP either through states enrolling them through the buy-in process under section 1843 of the Act or by using a limited number of SEPs and, outside of that, relief is only available in instances where an individual did not enroll due to a Federal Government error. Other than these very specific scenarios, no exceptions are legally permissible.

The proposed changes give the Secretary the flexibility to address other situations where a beneficiary missed an enrollment period and mirrors the authority that has long been available under the Medicare Part C and Part D programs. We believe this provision is likely to improve access to continuous coverage for individuals covered by Medicare Part A and Part B, either through expediting the effective date of coverage or by allowing for opportunities to enroll in coverage sooner. Therefore, we anticipate this proposal having a positive impact on communities who experience social risk factors impacted by lack of continuous health coverage. Our proposal fulfills the goals of the January 28, 2021 *Executive Order on Advancing Racial Equity and Support for Underserved Communities through The Federal Government*, which directs the Secretary of the Department of Health and Human Services, among other things, to pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality.⁵¹

⁵¹ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>

Further, section 402 of the CAA extends immunosuppressive drug coverage for individuals whose Medicare entitlement based on ESRD ends 36-months after the month in which they received a successful kidney transplant by providing immunosuppressive drug coverage under Medicare Part B for certain individuals. Under current rules, an individual loses Medicare coverage 36 months after a successful transplant (unless they are otherwise entitled to the coverage), but it does not negate the need for an individual to take immunosuppressive drugs long-term. Not having coverage for immunosuppressive drugs can cause individuals to reduce their usage in order to make their medication last longer or they may stop taking the medications entirely which can lead to organ rejection and transplant failure. The new Part B-ID benefit helps remedy this situation by ensuring that these individuals have access to immunosuppressive drug coverage for the rest of their life. Even with access to immunosuppressive drug benefits, low-income individuals may be unable to afford these immunosuppressive drugs due to their high cost. By extending certain MSP programs to this new Part B-ID benefit, states will cover the costs of the Part B-ID premiums and in some cases, cost-sharing as well. In particular, this MSP Part B-ID coverage would help individuals who lose Medicare coverage 36 months after a successful transplant and live in a non-expansion state with income too high to receive subsidies for purchasing a health plan in the Exchange. Without this MSP Part B-ID coverage, these individuals may be unable to pay Part B-ID premiums and cost-sharing and as such, at higher risk of transplant failure. As such, supporting continued Medicaid coverage is consistent with the *Executive Order on Strengthening Medicaid and the Affordable Care Act*.

In addition to implementing various sections of the CAA, we seek to modernize the Medicare Savings Programs through which states cover Medicare premiums and cost-sharing and update the various federal regulations that affect a state's payment of Medicare Part A and B

premiums for beneficiaries enrolled in the Medicare Savings Programs and other Medicaid eligibility groups. We think it is important to update these policies now to reflect statutory changes over the last three-plus decades as well as to codify certain administrative practices that have evolved over the years. We anticipate our proposals will also advance health equity by improving low income individuals' access to continuous, affordable health coverage and use of needed health care consistent with the *Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*. We also believe that our proposals would improve the customer service experience of dually eligible beneficiaries consistent with the goals of the *Executive Order on Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government*. Finally, we believe these are commonsense, good government proposals that will also reduce administrative burden on states and promote transparency and clarity regarding state payment of premiums or buy-in. For example, consolidating state buy-in policy in one document, the Medicaid state plan, will make it easier for states to update their buy-in policy and promote transparency for the public to better understand states' buy-in policy.

B. Overall Impact

We have examined the impacts of this rule 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 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.

The RFA requires agencies to analyze options for regulatory relief 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 nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million annually. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities. This rule’s costs would predominantly fall on the Federal government and states, and the associated burden falls primarily on the Federal government and individuals.

The Unfunded Mandates Reform Act of 1995 (Section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$165 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This proposed rule, if finalized, would not result in expenditures that meet or exceed this amount.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). These proposed regulations are not economically significant within the meaning of section 3(f)(1) of Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these proposed regulations, and the Department has provided the following assessment of their impact. The following chart demonstrates the year by year amounts, broken out by cost for drugs and savings

C. Detailed Economic Analysis

1. Beneficiary Enrollment Simplification (§§ 406.22 and 407.22)

We are proposing revisions to implement section 120 of the CAA. These revisions make the effective date of coverage the first of the month following an individual's enrollment during their IEP or during the GEP. We are also proposing SEPs that would provide individuals who meet certain exceptional conditions an opportunity to enroll without having to wait for the GEP.

a. Benefits

The changes to the IEP and GEP coverage dates would provide Medicare beneficiaries

access to coverage more quickly and may allow them faster access to needed medical care. The newly proposed SEPs for beneficiaries who have experienced an exceptional condition that caused them to delay enrollment in Medicare would also provide access to Medicare coverage earlier, reducing gaps in coverage, and beneficiaries may avoid LEPs by utilizing these SEPs.

b. Costs

Costs include increased months of coverage provided by the new SEPs and the earlier effective dates for the IEP and GEP and potential loss of LEP revenue. As detailed earlier, we estimate that approximately 31,449 individuals would be eligible to enroll earlier using the proposed exceptional condition SEPs.

In addition, CMS does not foresee an increase of costs to Medicare beneficiaries related to Part B premium increases. Specifically, we do not expect beneficiaries enrolling under these new provisions to have higher-than-average costs, so we assume this provision will not have an impact on the Part B premium.

c. Transfers

The CAA also modified section 1839(b) of the Act to exempt individuals who enroll pursuant to an SEP for exceptional conditions established under section 1838(m) of the Act, from paying an LEP. Therefore, beneficiaries who are able to utilize the newly established SEPs will benefit from an avoidance of an LEP. Based on the data described in section III B.1 of this proposed rule, we estimate approximately 31,449 premium Part A and Part B enrollments annually under the proposed SEPs. We anticipate that the loss of revenue associated with LEP and the additional months of coverage associated with individuals using the new SEPs will be a cost to the Medicare Trust Fund. Due to variables that CMS cannot predict, such as the timing of when beneficiaries will use an SEP to enroll in Medicare or what their LEP would have been had

the SEP not been made available, CMS is not able to estimate an exact cost to the Trust Funds that will result from enrolling beneficiaries through these proposed SEPs. However, based on the small number of beneficiaries impacted, and because this rule proposes that individuals will have to miss an enrollment period in order to access these new SEPs, we expect the increased costs to the Medicare to be negligible. Further, we note the beneficiaries who are enrolled via these SEPs would be paying premiums to the Trust Fund, which would be revenue that might have otherwise gone uncollected.

2. Extended Months of Coverage of Immunosuppressive Drugs for Kidney Transplant Patients (§§ 407.1, 407.55, 407.57, 407.59, 407.62, 407.65, 408.20, and 423.30)

We are proposing regulations that would establish the new Part B-ID benefit. These regulations would establish the eligibility requirements (including the requirement that the individual attest that they do not have other disqualifying health coverage), the reasons and process for termination of coverage, and the basis for the premium for the benefit.

a. Benefits

The American Society of Nephrology and the HHS Assistant Secretary for Planning and Evaluation report that providing beneficiaries with extended access to immunosuppressive drugs may reduce any associated costs they face from kidney failure, including maintaining labor force participation and improved quality of life.⁵²

⁵² Kadatz, M., Gill, J. S., Gill, J., Formica, R. N., & Klarenbach, S. (2019). Economic Evaluation of Extending Medicare Immunosuppressive Drug Coverage for Kidney Transplant Recipients in the Current Era. *Journal of the American Society of Nephrology*, 31(1), 218–228. <https://doi.org/10.1681/asn.2019070646>
See https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/189276/Savings_From_Extending_Coverage_For_Immunosuppressive_Drugs_Final.pdf from ASPE discussing cost benefits of extending drug coverage.

b. Costs

Extending immunosuppressive drug coverage would pose an additional cost to Medicare to pay for the additional drugs, reduced by the savings associated with reduction in reversion to dialysis from graft failure. CMS actuaries estimate a net cost of \$55 million to the Medicare program over the period 2022-2031. This estimate was provided by CMS actuaries, based on historical information from SSA. SSA's data shows that roughly 165,000 individuals had prior Medicare Part A coverage and had a kidney transplant between 2001 and 2019. Removing any individuals not currently alive or enrolled in Medicare Part A, within SSA's historical data approximately 52,000 individuals would remain potentially eligible to enroll in Part B-ID. In addition, CMS assumes approximately 1,000 individuals a month will be disenrolled from Medicare Part A 36 months after a successful transplant. After accounting for those individuals who are anticipated to have other comprehensive coverage, and thus would not be eligible for the Part B-ID benefit, we assume that of those who were terminated from Part A after a successful transplant between 2001 and 2019, roughly 1,050 individuals would initially be enrolled in the Part B-ID benefit. Using similar assumptions about other coverage and those that are newly eligible for the benefit (roughly 12,000 individuals in a year), we assume an estimated growth of 250 enrollees each year thereafter. Beneficiaries would also incur potential costs associated with the premium associated with the additional benefit. For beneficiaries enrolled in MSPs for coverage of premiums and cost sharing of the Part B-ID benefit, states will incur premium and cost sharing costs for the benefit as well as costs associated with systems and other changes

needed for reporting enrollment in these MSPs as described in further detail elsewhere in this document.

Part B-ID Benefit Costs and Savings Estimate (in millions)					
FY	Cost Due to Drugs	Savings due to Saved Transplants	Total Gross Benefits	Part B Premium Offset	Net Impact
2022	0	0	0	0	0
2023	0	0	0	0	0
2024	5	0	5	0	5
2025	5	0	5	0	5
2026	5	0	5	0	5
2027	5	0	5	0	5
2028	10	0	10	-5	5
2029	10	0	10	0	10
2030	10	0	10	0	10
2031	15	0	15	-5	10

c. Effects of Medicare Saving Programs Coverage for Immunosuppressive Drugs

As described previously, under section 402(f) of the CAA, we are proposing to modify three MSP eligibility groups (QMB, SMLB, and QI) to pay premiums and, if applicable, cost sharing for low-income beneficiaries enrolled in the Part B-ID benefit (MSP Part B-ID).

Individuals currently enrolled as QMBs, SLMBs, and QIs must meet income and resource requirements in addition to having entitlement to Medicare Part A. With this proposed change, individuals may enroll in QMB, SLMB, and QI for the Part B-ID benefit if they are enrolled in the Part B-ID benefit and meet the underlying income and resource requirements for QMB, SLMB, or QI. While states pay Medicare Part A and B premiums and cost sharing for certain MSP eligibility groups, state payment for the MSP Part B-ID benefit is limited to Part B-ID benefit premiums and/or cost sharing.

As discussed in more detail in section III.B.2. of this proposed rule, due to the limited scope of Part B-ID benefit entitlement and the income and resource eligibility limits for the MSP

population, we anticipate enrollment in the MSP Part B-ID benefit mainly occurring in the 12 non-expansion states among individuals who qualify as QMBs, with about 250 people a year enrolling and 1,000 people enrolling initially. We estimate the cost of paying for the Part B-ID benefit for these individuals across all states is $-\$657,000 (1,250 \times (\text{state portion of premium (Part B-ID benefit premium } (\$1,200) \times \text{states' average FMAP rate) } (1-0.562)) + \text{state portion of Part B-ID benefit cost sharing (20 percent of cost of CMS actuarial estimate of immunosuppressive drug therapy } (\$8,000 \times 0.2) \times \text{states' average FMAP rate } (1-0.562) - \text{Medicaid drug rebate of 50 percent of cost of immunosuppressive drug therapy } (\$8,000 \times 0.5) \times \text{states' average FMAP rate } (1-0.562))$. In sum, the drug rebate will more than offset the state share of the Part B-ID benefit premium and cost sharing obligations, yielding a net savings for states.

In addition to the liability for the Part B-ID benefit premium and cost sharing, states will also need to perform the following tasks: (1) modify their systems to report MSP Part B-ID benefit enrollment on the Third Party Systems (TPS) files; (2) modify their internal systems to receive and process new values in existing fields for Part B-ID benefit enrollment in the MMA file, TPS, Territories and States Beneficiary Query (TBQ), T-MSIS, as well as on SSA's state data exchanges; (3) process the change in the premium from the Part B standard premium to the Part B-ID benefit premium in TPS for billing; (4) modify their process to query SSA systems to confirm Part B-ID benefit enrollment prior to enrolling in the MSP Part B-ID benefit; (5) adjust Medicaid eligibility systems to include new MSP Part B-ID benefit enrollment codes; and (6) adjust Medicaid pharmacy claims to include this new Part B-ID benefit crossover claim. We anticipate all states will need to make systems changes and test these systems changes 4-6 months prior to implementation.

We estimate that it would take a maximum of 12 months of work (approximately 2,000 hours) by three computer programmers working at a BLS mean hourly rate of \$94.52 per hour to make the necessary systems changes. Since we estimate that 50 states plus the District of Columbia (D.C.)⁵³ will need to make a plan for manual changes, we project an aggregate burden of \$12,668,326.6 (51 (50 states and D.C.) * 2,000 hrs * \$94.52/hr * 3 * states' average FMAP rate). The cost and time attributable to these systems change will be influenced by whether the state is implementing other systems changes at the same time and their current Medicaid Management Information System (MMIS) system functionality. Assuming the state implements this change in isolation, we estimate that this change could take 12 months. However, if a state makes this change as a part of a broader systems update, the work specific to the proposal could be less burdensome. In particular, we note that states need to make systems updates under the Interoperability and Patient Access final rule, 85 FR 25510 (May 1, 2020) to comply with 42 CFR 406.26 and 407.40 to make file transfers daily by April 1, 2022.

If states chose to integrate these system updates at the same time, they could save money. We note that states are likely eligible for 90/10 federal medical assistance percentage (FMAP) for the MMIS as set forth in 1903(a)(3)(A) of the Act.

3. Simplifying Regulations Related to Medicare Enrollment Forms

We are proposing to revise §§ 406.7 and 407.11 to remove references to specific enrollment forms that are used to apply for entitlement under Medicare Part A and enrollment under Medicare Part B. This is an administrative change that will not impact the use of the forms. We do not anticipate a change in burden or cost associated with each of the forms.

⁵³ We note that we did not estimate impacts for the territories because currently, they have not elected MSP coverage for their residents. As such, they would not need to make these changes.

4. Modernizing State Payment of Medicare Premiums Benefits, Costs, and Transfers

To modernize state payment of Medicare premiums, we propose several changes to regulations at §§ 400.200, 406.21, 406.26, 407.40 through 48, 431.625. We also propose to add new §§ 435.123 through 435.126 and to revise § 435.4. Almost all of the proposed changes are to update the regulations to reflect statutory changes over the last 3-plus decades, and to codify certain administrative practices that have evolved over the years. Some of the most significant changes include replacing obsolete decades-old stand-alone buy-in agreements with treating buy-in provisions in the State plan as the State's buy-in agreement, and limiting retroactive Medicare Part B premium liability for states for full-benefit dually eligible beneficiaries. We are not projecting any impact for these provisions in this Regulatory Impact Analysis section because our proposals are consistent with current requirements and practice.

D. Regulatory Review Cost Estimation

We welcome any comments on the approach in estimating the number of entities which will review this proposed rule. Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$110.74 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it would take approximately 0.5 hours for the staff to review half of this proposed rule. For each entity that reviews the rule, the estimated cost is \$Y (0.5 hours x \$110.74). Therefore, we estimate that the total cost of reviewing this regulation is \$Z (\$Y x N). [*N is the number of estimated reviewers*]

E. Alternatives Considered

As noted previously, there were a number of additional SEPs that were considered but were not pursued for various reasons (discussed in greater length in section II.A.2.f of the

preamble). For example, we considered an SEP for individuals who previously decided not to enroll in Medicare but now want to enroll outside of the GEP or other enrollment period because they are experiencing a health event and want Medicare coverage. We also considered an SEP for individuals who lost Medicare coverage due to non-payment of premiums who are not eligible for another SEP or equitable relief and now want to re-enroll outside of the GEP. Further, several alternatives to the State Payment of Medicare premium policies and technical changes as were proposed and are described in sections II.D.1 through D.3 of this preamble. For example, we considered alternatives to further reduce the number of Part B buy-in groups from three to two and to limit buy-in liability for states in other situations in which Medicare benefits are not available, such as incarceration and beneficiaries who reside overseas.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 21, 2022.

List of Subjects**42 CFR Part 400**

Grant programs-health, Health facilities, Health maintenance organizations (HMO) Medicaid, Medicare Reporting, and recordkeeping requirements.

42 CFR Part 406

Health facilities, Diseases, and Medicare.

42 CFR Part 407

Medicare.

42 CFR Part 408

Medicare.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and, recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 431

Grant programs-health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 435

Aid to Families with Dependent Children, Grant programs-health, Medicaid, Reporting and recordkeeping requirements, Supplemental Security Income (SSI), and Wages.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 400—INTRODUCTION; DEFINITIONS

1. The authority citation for part 400 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh and 44 U.S.C. Chapter 35.

2. Section 400.200 is amended by--

a. Adding definitions of “Medicare Savings Programs” and “Qualified Individual”, in alphabetical order;

b. Revising the definition of “Qualified Medicare Beneficiary”; and

c. Adding the definition of “Specified Low-Income Medicare Beneficiary” in alphabetical order.

The additions and revision read as follows:

§ 400.200 General definitions.

* * * * *

Medicare Savings Programs (MSPs) has the same meaning described in § 435.4 of this chapter.

* * * * *

Qualifying Individual (QI) means an individual described in § 435.125 of this chapter.

Qualified Medicare Beneficiary (QMB) means an individual described in § 435.123 of this chapter.

* * * * *

Specified Low-Income Medicare Beneficiary (SLMB) means an individual described in § 435.124 of this chapter.

* * * * *

PART 406—HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT

3. The authority citation for part 406 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395i-2, 1395i-2a, 1395p, 1395q and 1395hh.

4. Section 406.7 is revised to read as follows:

§ 406.7 Forms to apply for entitlement under Medicare Part A.

Forms used to apply for Medicare entitlement are available free of charge by mail from CMS or at any Social Security branch or district office or online at the CMS and SSA websites. An individual who files an application for monthly social security cash benefits as defined in § 400.200 of this chapter also applies for Medicare entitlement if he or she is eligible for hospital insurance at that time.

5. Section 406.13 is amended by revising paragraph (f)(2) to read as follows:

§ 406.13 Individual who has end-stage renal disease.

* * * * *

(f) * * *

(2) The end of the 36th month after the month in which the individual received a kidney transplant. Beginning January 1, 2023, an individual who is no longer entitled to Part A benefits due to this paragraph may be eligible to enroll in Part B solely for purposes of coverage of immunosuppressive drugs as described in § 407.55.

* * * * *

6. Section 406.21 is amended by revising paragraphs (a) and (c)(3) to read as follows:

§ 406.21 Individual enrollment.

(a) *Basic provision.* An individual who meets the requirements of § 406.20 (b) or (c),

except as provided in § 406.27(b)(2), may enroll for premium hospital insurance only during his or her—

- (1) Initial enrollment period as set forth in paragraph (b) of this section;
- (2) A general enrollment period as set forth in paragraph (c) of this section;
- (3) A special enrollment period as set forth in §§ 406.24, 406.25, and 406.27 of this part;

or

(4) For HMO/CMP enrollees, a transfer enrollment period as set forth in paragraph (f) of this section.

* * * * *

(c) * * *

(3) If the individual enrolls or reenrolls during a general enrollment period—

(i) Before January 1, 2023, his or her entitlement begins on July 1 of the calendar year;

or

(ii) On or after January 1, 2023, his or her entitlement begins on the first day of the month after the month of enrollment.

* * * * *

7. Section 406.22 is amended by—

a. In paragraph (a) introductory text removing the phrase "age 65, the following rules apply:" and adding in its place the phrase "age 65, before January 1, 2023, the following rules apply:";

b. Redesignating paragraph (b) as paragraph (c);

c. Adding a new paragraph (b);

d. Revising the introductory text for newly redesignated paragraph (c); and

e. Adding paragraph (d).

The revisions and addition read as follows:

§ 406.22 Effect of month of enrollment on entitlement.

* * * * *

(b) *Individual age 65 or over.* For an individual who has attained age 65 on or after January 1, 2023, the following rules apply:

(1) If the individual enrolls during the first 3 months of their initial enrollment period, entitlement begins with the first month of eligibility.

(2) If an individual enrolls during the last 4 months of their initial enrollment period, entitlement begins with the month following the month of enrollment.

(c) *Individual under age 65.* For an individual who has not attained age 65 and who satisfies the requirements of §406.20(c) before January 1, 2023, the following rules apply:

* * *

(d) *Individual under age 65.* For an individual who has not attained age 65 and who first satisfies the requirements of §406.20(c) on or after January 1, 2023, the following rules apply:

(1) For individuals who enroll during the first 3 months of their IEP, entitlement begins with the first month of eligibility.

(2) If an individual enrolls during the month in which they first become eligible or any subsequent month of their IEP, entitlement begins with month following the month of enrollment

8. Section 406.26 is amended by –

a. Adding paragraph (a)(3); and

b. Revising paragraph (b)(2).

The addition and revision read as follows:

§ 406.26 Enrollment under State buy-in.

(a) * * *

(3) *Enrollment without discrimination.* A State that has a buy-in agreement in effect must enroll in premium health insurance any applicant who meets the eligibility requirement for the QMB eligibility group, with the State paying the premiums on the individual's behalf.

(b) * * *

(2) The first month in which the individual is entitled to premium hospital insurance under § 406.20(b) and has QMB status. Under a State buy-in agreement, as defined in § 407.40, QMB-eligible individuals can enroll in premium hospital insurance at any time of the year, without regard to Medicare enrollment periods.

* * * * *

8. Subpart C is amended by adding a new § 406.27 to read as follows:

§ 406.27 Special enrollment periods for exceptional conditions.

(a) *General rule.* Beginning January 1, 2023, in accordance with the Secretary's authority in sections 1837(m) and 1838(g) of the Act, the following SEPs, as defined under § 406.24(a)(4) of this subchapter, are provided for individuals that missed a Medicare enrollment period, (as specified in §§ 406.21, 406.24, or 406.25), due to exceptional conditions as determined by the Secretary and established under paragraphs (b) through (f) of this section. SEPs are provided for exceptional conditions that took place on or after January 1, 2023 except as specified in paragraph (e).

(b) *Special enrollment period for individuals impacted by an emergency or disaster.* An SEP exists for individuals prevented from submitting a timely Medicare enrollment request by an emergency or disaster declared by a Federal, state, or local government entity.

(1) *SEP parameters.* An individual is eligible for the SEP if they reside (or resided) in an area for which a Federal, State or local government entity newly declared a disaster or other emergency. The individual must demonstrate that they reside (or resided) in the area during the period covered by that declaration.

(2) *SEP duration.* The SEP begins on the earlier of the date an emergency or disaster is declared or, if different, the start date identified in such declaration. The SEP ends 2 months after the end date identified in the declaration, the end date of any extensions or the date when the declaration has been determined to have ended or has been revoked, if applicable.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

(c) *Special enrollment period for individuals affected by a health plan or employer misrepresentation.* An SEP exists for individuals whose non-enrollment in premium Part A is unintentional, inadvertent, or erroneous and results from misrepresentation or reliance on incorrect information provided by the individual's employer or GHP, or any person authorized to act on behalf of such entity.

(1) *SEP parameters.* An individual is eligible for the SEP if they can demonstrate both of the following:

(i) He or she did not enroll in premium Part A during another enrollment period in which they were eligible based on information received from an employer or GHP, or any person authorized to act on such organization's behalf.

(ii) An employer, GHP or their representative materially misrepresented information or provided incorrect information relating to enrollment in premium Part A.

(2) *SEP duration.* This SEP begins the day the individual notifies SSA of the employer or GHP misrepresentation and ends 2 months later.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

(d) *SEP for formerly incarcerated individuals.* An SEP exists for Medicare eligible individuals who are released from incarceration (as described in § 411.4(b)) on or after January 1, 2023.

(1) *SEP parameters.* An individual is eligible for this SEP if they demonstrate that they are eligible for Medicare and failed to enroll or reenroll in Medicare premium Part A due to their incarceration and there is a record of release either through discharge documents or data available to SSA.

(2) *SEP duration.* The SEP starts the day of the individual's release from incarceration and ends the last day of the sixth month after the month in which the individual is released from incarceration.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

(e) *Special enrollment period for termination of Medicaid coverage.* An SEP exists for individuals whose Medicaid eligibility is terminated.

(1) *SEP parameters.* An individual is eligible for this SEP if they can demonstrate that--

- (i) They are eligible for premium Part A under § 406.5(b); and
- (ii) Their Medicaid eligibility is terminated on or after January 1, 2023, or is terminated after the last day of the Coronavirus Disease 2019 public health emergency (COVID-19 PHE) as determined by the Secretary, whichever is earlier.

(2) *SEP duration.* If the termination of Medicaid eligibility occurs —

(i) After the last day of the COVID-19 PHE and before January 1, 2023, the SEP starts on January 1, 2023 and ends on June 30, 2023.

(ii) On or after January 1, 2023, the SEP starts when the individual is notified of termination of Medicaid eligibility and ends 6 months after the termination of eligibility.

(3) *Entitlement.* (i) *General rule.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is after the last day of the COVID-19 PHE or on after January 1, 2023, whichever is earlier.

(ii) *Special rule.* An individual whose Medicaid eligibility is terminated after the end of the COVID-19 PHE, but before January 1, 2023 (if applicable), has the option of requesting that entitlement begin back to the first of the month following termination of Medicaid eligibility provided the individual pays the monthly premiums for the period of coverage (as required under § 406.31).

(4) *Effect on previously accrued late enrollment penalties.* Individuals who otherwise would be eligible for this SEP, but enrolled during the COVID-19 PHE prior to January 1, 2023, are eligible to have late enrollment penalties collected under § 406.32(d) reimbursed and ongoing penalties removed.

(f) *Special enrollment period for other exceptional conditions.* An SEP exists for other exceptional conditions as CMS may provide.

(1) *SEP parameters.* An individual is eligible for the SEP if both of the following apply:

(i) The individual demonstrates that they missed an enrollment period in which they were eligible because of an event or circumstance outside of the individual's control which prevented them from enrolling in premium Part A.

(ii) It is determined that the conditions were exceptional in nature.

(2) *SEP duration.* The SEP duration is determined on a case-by-case basis.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

10. Section 406.33 is amended by--

a. Revising the introductory text for paragraph (a); and

b. Redesignating paragraph (c) as paragraph (d) and adding new paragraph (c).

The revision and addition read as follows:

§ 406.33 Determination of months to be counted for premium increase: Enrollment.

(a) *Enrollment before April 1, 1981 or after September 30, 1981 and before January 1, 2023.* The months to be counted for premium increase are the months from the end of the initial enrollment period through the end of the general enrollment period, the special enrollment period, or the transfer enrollment period in which the individual enrolls, excluding the following:

* * * * *

(c) *Enrollment on or after January 1, 2023.* The months to be counted for premium increase are the months from the end of the initial enrollment period through the end of the month in which the individual enrolls, excluding both of the following:

(1) The months described in paragraphs (a)(1) through (a)(6) of this section.

(2) Any months of non-coverage in accordance with an individual’s use of an exceptional conditions SEP under § 406.27 provided the individual enrolls within the duration of the SEP.

* * * * *

11. Section 406.34 is amended by—

- a. Revising the introductory text for paragraph (a); and
- b. Redesignating paragraph (e) as paragraph (f) and adding new paragraph (e).

The revision and addition read as follows:

§ 406.34 Determination of months to be counted for premium increase: Reenrollment.

(a) *First reenrollment before April 1, 1981 or after September 30, 1981 and before January 1, 2023.* The months to be counted for premium increase are:

* * * * *

(e) *Reenrollments on or after January 1, 2023.*

(1) The months to be counted for premium increase are as follows:

- (i) The months specified in § 406.33(c).
- (ii) The months specified in paragraphs (b) and (d) of this section (if applicable).
- (iii) The months from the end of the first period of entitlement through the end of the month during the general enrollment period in which the individual reenrolled.

(2) The months excluded from premium increase are the months of non-coverage in accordance with an individual’s use of an exceptional conditions SEP under § 406.27, provided the individual enrolls within the duration of the SEP.

* * * * *

PART 407—SUPPLEMENTARY MEDICAL INSURANCE (SMI) ENROLLMENT AND ENTITLEMENT

12. The authority citation for part 407 is revised to read as follows:

Authority: 42 U.S.C 1302, 1395p, 1395q, and 1395hh.

13. Section 407.1 is amended by adding new paragraph (a)(6) and revising paragraph (b) to read as follows:

§ 407.1 Basis and scope.

(a) * * *

(6) Sections 1836(b) and 1837(n) of the Act provide for coverage of immunosuppressive drugs as described in section 1861(s)(2)(J) of the Act under Part B beginning on or after January 1, 2023, for eligible individuals whose benefits under Medicare Part A and eligibility to enroll in Part B on the basis of ESRD would otherwise end with the 36th month after the month in which the individual receives a kidney transplant by reason of section 226A(b)(2) of the Act.

(b) *Scope.* This part sets forth the eligibility, enrollment, and entitlement requirements and procedures for the following:

(1) Supplementary medical insurance. (The rules about premiums are in part 408 of this chapter.)

(2) The immunosuppressive drug benefit provided for under sections 1836(b) and 1837(n) of the Act, hereinafter referred to as the Part B-Immunosuppressive Drug Benefit (Part B-ID).

14. Section 407.11 is revised to read as follows:

§ 407.11 Forms used to apply for enrollment under Medicare Part B.

Forms used to apply for enrollment under the supplementary medical insurance program are available free of charge by mail from CMS, or at any Social Security branch or district office and online at the CMS and SSA websites. As an alternative, the individual may request enrollment by signing a simple statement of request, if he or she is eligible to enroll at that time.

15. Adding a new § 407.23 to read as follows:

§ 407.23 Special enrollment periods for exceptional conditions.

(a) *General rule:* Beginning January 1, 2023, in accordance with the Secretary's authority in sections 1837(m) and 1838(g) of the Act, the following SEPs, as defined under § 406.24(a)(4) of this subchapter, are provided for individuals who missed a Medicare enrollment period (as specified in §§ 407.21, 407.15 or 407.20) due to exceptional conditions as determined by the Secretary and established under paragraphs (b) through (f) of this section. SEPs are provided for exceptional conditions that took place on or after January 1, 2023 except as specified in paragraph (e).

(b) *Special enrollment period for individuals impacted by an emergency or disaster.* An SEP exists for individuals prevented from submitting a timely Medicare enrollment request by an emergency or disaster declared by a Federal, State or local government entity.

(1) *SEP parameters.* An individual is eligible for the SEP if they reside (or resided) in an area for which a Federal, State or local government entity newly declared a disaster or other emergency. The individual must demonstrate that they reside (or resided) in the area during the period covered by that declaration.

(2) *SEP duration.* The SEP begins on the earlier of the date an emergency or disaster is declared or, if different, the start date identified in such declaration. The SEP ends 2 months after the end date identified in the declaration, the end date of any extensions or the date when the declaration has been determined to have ended or has been revoked, if applicable.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

(c) *Special enrollment period for individuals affected by a health plan or employer misrepresentation.* An SEP exists for individuals whose non-enrollment in SMI is unintentional,

inadvertent, or erroneous and results from misrepresentation or reliance on incorrect information provided by the individual's employer or GHP, or any person authorized to act on behalf of such entity.

(1) *SEP parameters.* An individual is eligible for the SEP if they can demonstrate the both of the following:

(i) He or she did not enroll in SMI during another enrollment period in which they were eligible based on information received from an employer or GHP, or any person authorized to act on such organization's behalf.

(ii) An employer, GHP or their representative materially misrepresented information or provided incorrect information relating to enrollment in SMI.

(2) *SEP duration.* This SEP begins the day the individual notifies SSA of the employer or GHP misrepresentation, or the incorrect information provided and ends 2 months later.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

(d) *SEP for formerly incarcerated individuals.* An SEP exists for Medicare eligible individuals who are released from incarceration (as described in § 411.4(b)), on or after January 1, 2023.

(1) *SEP parameters.* An individual is eligible for this SEP if they demonstrate that they are eligible for Medicare and failed to enroll or reenroll in SMI due to their incarceration, and there is a record of release either through discharge documents or data available to SSA.

(2) *SEP duration.* The SEP starts the day of the individual's release from incarceration and ends the last day of the sixth month after the month in which the individual is released from incarceration.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

(e) *Special enrollment period for termination of Medicaid coverage.* An SEP exists for individuals whose Medicaid eligibility is terminated.

(1) *SEP parameters.* An individual is eligible for this SEP if they can demonstrate that—

(i) They are eligible for Part B under § 407.4(a); and

(ii) Their Medicaid eligibility is being terminated after January 1, 2023, or after the last day of the Coronavirus Disease 2019 public health emergency (COVID-19 PHE) as determined by the Secretary, whichever is earlier.

(2) *SEP duration.* If the termination of Medicaid eligibility occurs—

(i) After the last day of the COVID-19 PHE and before January 1, 2023, the SEP starts on January 1, 2023 and ends on June 30, 2023.

(ii) On or after January 1, 2023, the SEP starts when the individual is notified of termination of Medicaid eligibility and ends 6 months after the termination of eligibility.

(3) *Entitlement.* (i) *General rule.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is the month following the last month of the COVID-19 PHE or on or after January 1, 2023, whichever is earlier.

(ii) *Special rule.* An individual whose Medicaid eligibility is terminated after the end of the COVID-19 PHE, but before January 1, 2023 (if applicable), has the option of requesting that entitlement begin back to the first of the month following termination of Medicaid eligibility provided the individual pays the monthly premiums for the period of coverage (as required under part 408 of this subchapter).

(4) *Effect on previously accrued late enrollment penalties.* Individuals who otherwise would be eligible for this SEP, but enrolled during the COVID-19 PHE prior to January 1, 2023, are eligible to have late enrollment penalties collected under § 408.22 of this subchapter reimbursed ongoing penalties removed.

(f) *Special enrollment period for other exceptional conditions.* An SEP exists for other exceptional conditions as CMS may provide.

(1) *SEP parameters.* An individual is eligible for the SEP if both of the following apply:

(i) The individual demonstrates that they missed an enrollment period in which they were eligible because of an event or circumstance outside of the individual's control which prevented them from enrolling in SMI.

(ii) It is determined that the conditions were exceptional in nature.

(2) *SEP duration.* The SEP duration is determined on a case by case basis.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

16. Section 407.25 is amended by revising paragraphs (a) and (b) to read as follows:

§ 407.25 Beginning of entitlement: Individual enrollment.

The following apply whether an individual is self-enrolled or automatically enrolled in SMI:

(a) *Enrollment during initial enrollment period.* For individuals who first meet the eligibility requirements of § 407.10 in a month beginning--

(1) Before January 1, 2023, the following entitlement dates apply:

(i) If an individual enrolls during the first 3 months of the initial enrollment period, entitlement begins with the first month of eligibility.

(ii) If an individual enrolls during the fourth month of the initial enrollment period, entitlement begins with the following month.

(iii) If an individual enrolls during the fifth month of the initial enrollment period, entitlement begins with the second month after the month of enrollment.

(iv) If an individual enrolls in either of the last 2 months of the initial enrollment period, entitlement begins with the third month after the month of enrollment.

(v) *Example.* An individual first meets the eligibility requirements for enrollment in April. The individual’s initial enrollment period is January through July. The month in which the individual enrolls determines the month that begins the period of entitlement, as follows:

Enrolls in initial enrollment period	Entitlement begins on—
January	April 1 (month eligibility requirements first met).
February	April 1.
March	April 1.
April	May 1 (month following month of enrollment).
May	July 1 (second month after month of enrollment).
June	September 1 (third month after month of enrollment).
July	October 1 (third month after month of enrollment).

(2) On or after January 1, 2023, the following entitlement dates apply:

(i) If an individual enrolls during the first 3 months of the initial enrollment period, entitlement begins with the first month of eligibility.

(ii) If an individual enrolls during the last 4 months of the initial enrollment period, entitlement begins with the month following the month in which they enroll.

(b) *Enrollment or reenrollment during general enrollment period.* (1) If an individual enrolls or reenrolls during a general enrollment period before April 1, 1981, or after September 30, 1981 and before January 1, 2023, entitlement begins on July 1 of that calendar year.

* * * * *

(3) If an individual enrolls or reenrolls during a general enrollment period on or after January 1, 2023, entitlement begins on the first day of the month following the month in which they enroll.

* * * * *

17. Section 407.40 is amended by—

- a. Adding paragraphs (a)(6) through (9);
- b. Revising paragraph (b) introductory text;
- c. In paragraph (b) by--
 - (i) Adding the definitions of “1634 State” in alphabetical order;
 - (ii) Revising the definition of “AFDC”;
 - (iii) Adding the definition of “Buy-in group” in alphabetical order;
 - (iv) Removing the definition of “Qualified Medicare Beneficiary”;
 - (v) Revising the definition of “State buy-in agreement or buy-in agreement”;
- g. Revising paragraph (c)(1); and
- h. Adding paragraph (c)(4) and (5).

The additions and revisions read as follows:

§ 407.40 Enrollment under a State buy-in agreement.

(a) * * *

(6) Section 4501 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508) established the Specified Low-Income Medicare Beneficiary (SLMB) eligibility group effective January 1993.

(7) Section 4732 of the Balanced Budget Act of 1997 (Pub. L. 105-33) established the Qualifying Individual or QI eligibility group effective January 1998.

(8) Section 112 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275) increased the resource standard for QMB, SLMB, and QI to the same level as the full Part D LIS resource standard effective January 1, 2010.

(9) Title II, section 211, of the Medicare Access and CHIP Reauthorization Act (Pub. L. 114-10), effective April 16, 2015, permanently extended the QI eligibility group.

(10) Title II, section 402 of the Consolidated Appropriations Act of (Pub. L. 116-260), effective January 1, 2023, expands QMB, SLMB, and QI to cover individuals who are enrolled in Medicare Part B for coverage of immunosuppressive drugs.

(b) *Definitions.* As used in this subpart C, unless the context indicates otherwise –

* * * * *

1634 State means a State that has an agreement with SSA, in accordance with section 1634 of the Act, for SSA to determine Medicaid eligibility on behalf of the State for individuals residing in the State whom the SSA has determined eligible for SSI.

Buy-in group means a coverage group described in section 1843 of the Act that is identified by the State and is composed of multiple Medicaid eligibility groups specified in the buy-in agreement.

Cash assistance * * *

AFDC stands for aid to families with dependent children under Part A of title IV of the Act, as it was in effect on July 16, 1996.

* * * * *

State buy-in agreement or buy-in agreement means an agreement authorized or modified by sections 1843 or 1818(g) of the Act, under which a State secures Part B or premium Part A coverage for individuals who are members of the buy-in group specified in the agreement, by enrolling them and paying the premiums on their behalf. A State’s submission of a State plan amendment addressing its buy-in process, if approved by CMS, constitutes the “buy-in agreement” between the State and CMS for purposes of sections 1843 and 1818(g) of the Act.

* * * * *

(c) * * *

(1) A State that has a buy-in agreement in effect must enroll any individual who is eligible to enroll in SMI under § 407.10 and who is a member of the buy-in group, with the State paying the premiums on the individual’s behalf. Individuals enrolled in the buy-in group can enroll in Part B at any time of the year, without regard to Medicare enrollment periods.

* * * * *

(4) In a 1634 State, CMS enrolls SSI beneficiaries in Medicare Part B, on behalf of the State, with the State paying the beneficiary’s Part B premiums.

(5) Premiums paid under a State buy-in agreement are not subject to increase because of late enrollment or reenrollment.

* * * * *

18. Section 407.42 is revised to read as follows:

§ 407.42 Buy-in groups available to the 50 States, the District of Columbia, and the Northern Mariana Islands.

(a) *Basic rule.* The 50 States, the District of Columbia, and the Northern Mariana Islands must select one of the buy-in groups described in paragraph (b) in their buy-in agreements.

(b) *Buy-in groups available:*

(1) Group 1: Cash Assistance and Deemed Recipients of Cash Assistance: This buy-in group includes all of the following:

(i) Individuals who receive SSI or SSP or both and are covered under the State's Medicaid state plan as categorically needy.

(ii) Individuals who under the Act or any other provision of Federal Law are treated, for Medicaid eligibility purposes, as though the individual was receiving SSI or SSP and are covered under the State's Medicaid state plan as categorically needy.

(iii) At State option, individuals whom the State must consider to be recipients of AFDC, including those who receive adoption assistance, foster care or guardianship care under part E of title IV of the Act, in accordance with § 435.145, or who receive Medicaid coverage for low income families, in accordance with section 1931(b) of the Act.

(2) Group 2: Cash Assistance and Deemed Recipients of Cash Assistance and three Medicare Savings Program eligibility groups. This buy-in group includes both of the following:

(i) Group 1.

(ii) Individuals enrolled in the—

(A) Qualified Medicare Beneficiary eligibility group described in § 435.123;

(B) Specified Low-Income Beneficiary eligibility group described in § 435.124; and

(C) Qualifying Individual eligibility group described in § 435.125.

(3) Group 3: All Medicaid Eligibility Groups: This buy-in group includes all individuals eligible for Medicaid.

[§ 407.45 Removed]

19. Section 407.45 is removed.

20. Section 407.47 is amended by –

a. Revising paragraph (a)(2); and

b. Adding paragraphs (f) and (g).

The revisions and additions read as follows:

§ 407.47 Beginning of coverage under a State buy-in agreement.

(a) * * *

(2) The effective date of the buy-in agreement or agreement modification that covers the buy-in group to which the individual belongs, and which may not be earlier than the third month after the month in which the agreement or modification is executed. The State must apply the earliest applicable start date for the applicable buy-in group.

* * * * *

(f) Limitations on retroactive adjustments in the case of retroactive Medicare Part A entitlement.

(1) In cases in which a Medicaid beneficiary is retroactively entitled to Medicare Part A, State liability for retroactive Medicare Part B premiums for Medicaid beneficiaries under a buy-in agreement is limited to a period of no greater than 36 months prior to the date of the Medicare eligibility determination.

(2) The Secretary may grant good cause exceptions for periods of greater or less than 36 months if application of paragraph (f)(1) would result in harm to a beneficiary or if the State cannot benefit from Medicare and further limiting State liability would not result in harm to the beneficiary.

(g) Part B enrollment under a buy-in agreement. Individuals in a buy-in group can enroll in Part B at any time of the year, without regard to Medicare enrollment periods.

* * * * *

21. Section 407.48 is amended by –

- a. Revising paragraphs (c)(1) and (2); and
- b. Adding paragraph (e).

The revisions and addition read as follows:

§ 407.48 Termination of coverage under a State buy-in agreement.

* * * * *

(c) * * *

(1) On the last day of the last month for which he or she is eligible for inclusion in the buy-in group, if CMS determines ineligibility or receives a State ineligibility notice by a processing cut-off date as described in paragraph (e) of this section, by the second month after the month in which the individual becomes ineligible for inclusion in the buy-in group.

(2) On the last day of the second month before the month in which CMS receives a State ineligibility notice later than the time specified in paragraph (c)(1) of this section. If CMS receives a notice after the processing cut-off date conveyed under paragraph (e) of this section, CMS considers it to have been received the following month.

* * * * *

(e) *Processing cut-off dates for each calendar month.* On a quarterly basis, CMS is to prospectively convey to States a schedule of processing cut-off dates for each calendar month.

22. Part 407 is amended by adding a new Subpart D to read as follows:

Subpart D – Part B Immunosuppressive Drug Benefit

§ 407.55 Eligibility to enroll.

§ 407.57 Part B-ID benefit enrollment.

§ 407.59 Attestation.

§ 407.62 Termination of coverage.

Subpart D – Part B Immunosuppressive Drug Benefit

§ 407.55 Eligibility to enroll.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, an individual is eligible to enroll, be deemed enrolled, or reenroll in the Part B-ID benefit if their Part A entitlement ends as described in § 406.13(f)(2) of this chapter.

(b) *Exception.* An individual is not eligible for the Part B-ID benefit if the individual is enrolled in or for any of the following:

(1) A group health plan or group or individual health insurance coverage, as such terms are defined in section 2791 of the Public Health Service Act.

(2) Coverage under the TRICARE for Life program under section 1086(d) of title 10, United States Code.

(3) A State plan (or waiver of such plan) under title XIX and is eligible to receive benefits for immunosuppressive drugs described in section 1836(b) of the Act under such plan (or such waiver).

(4) A State child health plan (or waiver of such plan) under title XXI and is eligible to receive benefits for such drugs under such plan (or such waiver).

(5) The patient enrollment system of the Department of Veterans Affairs established and operated under section 1705 of title 38, United States Code and is either of the following:

(i) Not required to enroll under section 1705 of title 38 to receive immunosuppressive drugs described in section 1836(b) of the Act.

(ii) Otherwise eligible under a provision of title 38, United States Code, other than

section 1710 of such title, to receive immunosuppressive drugs described in section 1836(b) of the Act.

(c) *Appeals.* Denials for enrollment in the Part B-ID benefit will be considered an initial determination that is appealable under § 405.904(a)(1).

§ 407.57 Part B-ID benefit enrollment.

(a) *Deemed enrollment.* An individual whose Part A entitlement ends in accordance with § 406.13(f)(2) on or after January 1, 2023, is deemed to have enrolled into the Part B-ID benefit effective the first day of the month in which the individual first satisfies § 407.55, provided he or she provides the attestation required under § 407.59 prior to the termination of their Part A benefits.

(b) *Individual enrollment.* An individual whose Part A entitlement ends in accordance with § 406.13(f)(2), and who meets the requirements of § 407.55 and provides the attestation required under § 407.59, may enroll in the Part B-ID benefit under the following conditions:

(1) If the individual's entitlement ends prior to January 1, 2023, he or she may enroll in the Part B-ID benefit beginning on October 1, 2022.

(2) If individual's entitlement ends on or after January 1, 2023, the individual may enroll at any time after their entitlement ends.

(c) *Reenrollment.* An individual who had previously enrolled in the Part B-ID benefit, but terminated that benefit, can reenroll at any time, provided the individual meets the requirements of § 407.55 and provides the attestation required under § 407.59.

(d) *Attestation.* To enroll in the Part B-ID benefit, an individual must submit the required attestation as described in § 407.59.

(e) *Entitlement date.* The entitlement to the Part B-ID benefit will start as follows:

(1) For enrollments provided under paragraph (a) of this section, entitlement is effective the month Part A benefits are terminated.

(2) For enrollments provided under paragraphs (b) and (c) of this section, the Part B-ID benefit is effective the month following the month in which the individual provides the attestation required in § 407.59.

(3) *Exception.* Enrollments submitted October 1, 2022 through December 31, 2022, are effective January 1, 2023.

§ 407.59 Attestation.

As a condition of enrollment, an individual must attest to SSA in either a verbal attestation or signed paper form provided by SSA, that --

(a) The individual is not enrolled and does not expect to enroll in other coverage described in § 407.55(b); and

(b) If the individual does enroll in other coverage described in § 407.55(b), the individual will notify SSA within 60 days of enrollment in such other coverage.

§ 407.62 Termination of coverage.

(a) *Other coverage.* An individual who enrolls in other coverage as described in § 407.55(b) will have his or her enrollment in the Part B-ID benefit terminated on either of the following bases:

(1) If the individual notifies SSA of such coverage consistent with § 407.59(b), their enrollment in the Part B-ID benefit will be terminated effective the first day of the month after the month of notification unless the individual requests a different, prospective termination date that is not after the effective date of enrollment in other health insurance coverage, as described in § 407.55(b).

(2) If the individual does not notify SSA of this coverage consistent with § 407.59(b), their enrollment in the Part B-ID benefit will be terminated effective the first day of the month after the month in which there is a determination of the individual's enrollment in coverage described in § 407.55(b).

(b) *Death.* Enrollment in the Part B-ID benefit ends on the last day of the month in which the individual dies.

(c) *Nonpayment of premiums.* If an individual fails to pay the premiums, the Part B-ID benefit enrollment will end as provided in the rules for Part B premiums set forth in part 408 of this chapter.

(d) *Request by individual.* An individual may request disenrollment at any time by notifying SSA that he or she no longer wants to be enrolled in the Part B-ID benefit. Such individual's enrollment in the Part B-ID benefit ends with the last day of the month in which the individual provides the disenrollment request, except for an individual who loses coverage under a State buy-in agreement, as described in § 407.50(b)(2)(i).

(e) *Entitlement to Hospital Insurance benefits.* Enrollment in the Part B-ID benefit ends effective the last day of the month prior to the month that the individual becomes entitled to benefits under §§ 406.5, 406.12 or 406.13 of this chapter.

(f) *Appeals.* An involuntary termination of the Part B-ID benefit for reasons described at § 407.62 (a)(2), (b) or (c) of this subsection, will be considered an initial determination that is appealable under § 405.904(a)(1). An individual can request to continue receiving Part B-ID benefits while waiting for an appeals decision.

PART 408—PREMIUMS FOR SUPPLEMENTARY MEDICAL INSURANCE

23. The authority citation for part 408 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

24. Section 408.20 is amended by adding new paragraph (f) to read as follows:

§ 408.20 Monthly premiums.

* * * * *

(f) *Part B-ID premiums.*

(1) *Premium amount.* Beginning in 2022, and every year thereafter, the Secretary, as mandated by section 1839(j) of the Act, will determine and promulgate a monthly premium rate in September for the succeeding calendar year for individuals enrolled only in the Part B-ID benefit. Such premium is equal to 15 percent of the monthly actuarial rate for enrollees age 65 and over for that succeeding calendar year.

(2) *Premium adjustments.* (i) The Part B-ID benefit premium is subject to adjustments specified in §§ 408.20(e) (Nonstandard premiums for certain cases), 408.27 (Rounding the monthly premium), and 408.28 (Increased premiums due to the income-related monthly adjustment amount (IRMAA)).

(ii) The Part B-ID benefit premium is not subject to § 408.22 (Increased premiums for late enrollment and for reenrollment).

(3) *Premium collection.* Premiums for the Part B-ID benefit are collected as set out in § 408.6 and subpart C of this part.

25. Section 408.24 is amended by--

- a. Revising the introductory language for paragraph (a);
- b. Redesignating paragraph (b) as paragraph (c) and adding new paragraph (b);
- c. Revising the introductory language for newly redesignated paragraph (c); and
- d. Adding new paragraph (d).

The revisions and additions read as follows:

(3) *Premium deductions.* Part B-ID premiums are to be deducted following the rules set forth in § 408.40

§ 408.24 Individuals who enrolled or reenrolled before April 1, 1981 or after September 30, 1981.

(a) *Enrollment.* For an individual who first enrolled before April 1, 1981 or after September 30, 1981 and before January 1, 2023, the period includes the number of months elapsed between the close of the individual's initial enrollment period and the close of the enrollment period in which he or she first enrolled, and excludes the following:

* * * * *

(b) *Enrollment on or after January 1, 2023.* For an individual who first enrolled on or after January 1, 2023, the period *includes* the number of months elapsed between the close of the individual's initial enrollment period and the close of the month in which he or she first enrolled and *excludes--*

- (1) The periods of time described in (a)(1) through (a)(10) of this section; and
- (2) Any months of non-coverage in accordance with an individual's use of an exceptional conditions SEP under 407.23 provided the individual enrolls within the duration of the SEP.

(c) *Reenrollment.* For an individual who reenrolled before April 1, 1981 or after September 30, 1981 and before January 1, 2023, the period--

* * * * *

(d) *Reenrollment on or after January 1, 2023.* For an individual who reenrolled on or after January 1, 2023, the period--

(1) Includes the number of months specified in paragraphs (c)(1)(i) through (c)(1)(iii) of this section; and

(2) Excludes—

(i) The number of months specified in paragraphs (c)(2)(i) and (c)(2)(ii) of this section; and

(ii) Any months of non-coverage in accordance with an individual’s use of an exceptional conditions SEP under 407.23 provided the individual enrolls within the duration of the SEP.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

26. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

27. Section 410.30 is amended by revising paragraph (b) to read as follows:

§ 410.30 Prescription drugs used in immunosuppressive therapy.

* * * * *

(b) *Eligibility.* For drugs furnished on or after December 21, 2000, coverage is available only for prescription drugs used in immunosuppressive therapy, furnished to an individual who received an organ or tissue transplant for which Medicare payment is made, provided the individual is eligible to receive Medicare Part B benefits, including, beginning January 1, 2023, an individual who meets the requirements specified in § 407.55.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

28. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w-101 through 1395w-152, and 1395hh.

29. Section 423.30 is amended by revising paragraph (a)(1)(i) to read as follows:

§ 423.30 Eligibility and enrollment.

(a) * * *

(1) * * *

(i) Is entitled to Medicare benefits under Part A or enrolled in Medicare Part B (but not including an individual enrolled solely for coverage of immunosuppressive drugs under § 407.1(a)(6)).

* * * * *

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

30. The authority citation for part 431 is revised to read as follows:

Authority: 42 U.S.C. 1302.

31. Section 431.625 is amended—

a. By revising paragraph (d)(1) by removing the reference "title I, IV-A., X" and adding in its place the reference "title I, X";

b. By removing paragraphs (d)(2)(i), (vi), and (x);

c. By redesignating paragraphs (d)(2)(ii), (iii), (iv), and (v) as paragraphs (d)(2)(i), (ii), (iii), and (iv), respectively, and redesignating paragraphs (d)(2)(vii), (viii), and (ix) as paragraphs (d)(2)(v), (vi), and (vii), respectively;

c. In newly redesignated paragraph (d)(2)(i) by--

(i) Removing the reference "435.114,";

(ii) Removing the

d. By revising newly redesignated paragraph (d)(2)(iii);

e. In newly redesignated paragraph (d)(2)(iv) by removing "chapter" and adding in its place "subchapter";

- f. By revising newly redesignated paragraphs (d)(2)(vi) and (vii);
- g. By adding paragraphs (d)(2)(viii) and (ix); and
- h. In paragraph (d)(3) by removing the reference “435.914” and adding in its place the reference “435.915”.

The additions read as follows:

§ 431.625 Coordination of Medicaid with Medicare Part B.

* * * * *

(d) * * *

(2) * * *

(iii) Beneficiaries whom States must consider to be recipients of AFDC, including those who receive adoption assistance, foster care or guardianship care, under part E of title IV of the Act, in accordance with § 435.145 of this subchapter, or who receive Medicaid coverage for low income families, in accordance with section 1931(b) of the Act.

* * * * *

(vi) Disabled children living at home to whom the State provides Medicaid under § 435.225 of this subchapter.

(vii) Beneficiaries required to be covered under §§ 435.115 and 436.114(f) and (h) of this subchapter, that is, those who remain eligible for 4 months of temporary Medicaid coverage because of the increased collection of spousal support under part D of title IV of the Act.

(viii) Individuals required to be covered under the QMB, SLMB, and QI eligibility groups, each separately defined in §§ 435.123 through 435.125 of this chapter.

(ix) Adult children with disabilities, as described in 1634(c) of the Act.

* * * * *

PART 435—MANDATORY COVERAGE OF THE AGED, BLIND AND DISABLED

32. The authority citation for part 435 is revised to read as follows:

Authority: 42 U.S.C. 1302.

33. Section 435.4 is amended to add a new definition “of Medicare Savings Programs” as follows:

§ 435.4 Definitions and use of terms.

* * * * *

Medicare Savings Programs means four Medicaid eligibility groups authorized under section 1902(a)(10)(E) and 1905(p) and (s) of the Act that serve certain low-income Medicare beneficiaries. These groups include the Qualified Medicare Beneficiary, Specified Low-Income Medicare Beneficiary, Qualifying Individual, and Qualified Disabled and Working Individual eligibility groups, each separately codified in §§ 435.123 through 435.126.

* * * * *

34. Section 435.123 is added to read as follows:

§ 435.123 Individuals eligible as qualified Medicare beneficiaries.

(a) *Basis.* This section implements sections 1902(a)(10)(E)(i) and 1905(p)(1) of the Act.

(b) *Eligibility.* The agency must provide medical assistance to individuals who meet all of the following:

(1) Are entitled to Medicare Part A based on the eligibility requirements set forth in § 406.5(a) or § 406.20(b) of this chapter or who are enrolled in Medicare Part B for coverage of immunosuppressive drugs based on eligibility requirements described in § 407.55 of this chapter.

(2) Have an income, subject to paragraphs (b)(2)(i) and (ii) of this section, that does not exceed 100 percent of the Federal poverty level.

(i) During a transition month (as defined in paragraph (b)(2)(ii) of this section), any income attributable to a cost of living adjustment in Social Security retirement, survivors, or disability benefits does not count in determining an individual's income.

(ii) A transition month is any month of the year beginning when the cost of living adjustment takes effect, through the month following the month of publication of the revised official poverty level.

(3) Have resources, determined using financial methodologies no more restrictive than SSI, that do not exceed the Medicare Part D low-income subsidy (LIS) resource standard defined in section 1860D-14(a)(3)(D) of the Act and in § 423.773(d)(2)(ii) of this chapter.

(c) *Scope.* Medical assistance included in paragraph (b) includes all of the following:

(1) For individuals entitled to Medicare Part A as described in paragraph (b)(1) of this section, coverage for Parts A and B premiums and cost sharing, including deductibles and coinsurance, and copays.

(2) For individuals enrolled in Medicare Part B for coverage of immunosuppressive drugs as described in paragraph (b)(1) of this section, only coverage of premiums and cost sharing related to enrollment in Medicare Part B for coverage of immunosuppressive drugs.

35. Section 435.124 is added to read as follows:

§ 435.124 Individuals eligible as specified low-income Medicare beneficiaries.

(a) *Basis.* This section implements sections 1902(a)(10)(E)(iii) and 1905(p)(3)(A)(ii) of the Act.

(b) *Eligibility.* The agency must provide medical assistance to individuals who meet the eligibility requirements in § 435.123(b), except that income exceeds 100 percent, but is less than 120 percent of the poverty level.

(c) *Scope.* Medical assistance included in paragraph (b) of this section includes the following:

(1) For individuals entitled to Medicare Part A as described in paragraph (b)(1) of this section, coverage for the Part B premium.

(2) For individuals enrolled under Medicare Part B for coverage of immunosuppressive drugs as described in paragraph (b)(1) of this section, only coverage of the Part B premium related to enrollment in Medicare Part B for coverage of immunosuppressive drugs.

36. Section 435.125 is added to read as follows:

§ 435.125 Individuals eligible as qualifying individuals.

(a) *Basis.* This section implements sections 1902(a)(10)(E)(iv) and 1905(p)(3)(A)(ii) of the Act.

(b) *Eligibility.* The agency must provide medical assistance to individuals who meet the eligibility requirements in § 435.123(b), except that income is at least 120 percent, but is less than 135 percent of the federal poverty level.

(c) *Scope.* Medical assistance included in paragraph (b) includes the following:

(1) For individuals entitled to Medicare Part A as described in paragraph (b)(1) of this section, coverage for the Part B premium.

(2) For individuals enrolled under Medicare Part B for coverage of immunosuppressive drugs as described in paragraph (b)(1) of this section, only payment of the Part B premium related to enrollment in Medicare Part B for coverage of immunosuppressive drugs.

37. Section 435.126 is added to read as follows:

§ 435.126 Individuals eligible as Qualified Disabled and Working Individuals.

(a) *Basis.* This section implements sections 1902(a)(10)(E)(ii) and 1905(s) of the Act.

(b) *Eligibility.* The agency must provide medical assistance to individuals who meet all of the following:

(1) Are entitled to Medicare Part A based on the eligibility requirements set forth in § 406.20(c) of this chapter.

(2) Have income, subject to paragraphs (b)(2)(1)(i) and (ii) of this section, that is less than or equal to 200 percent of the federal poverty level.

(i) During a transition month (as defined in paragraph (b)(2)(ii) of this section), any income attributable to a cost of living adjustment in Social Security retirement, survivors, or disability benefits does not count in determining an individual's income.

(ii) A transition month is any month of the year beginning when the cost of living adjustment takes effect, through the month following the month of publication of the revised official poverty level.

(3) Have resources that do not exceed twice the SSI resource standard described in section 1613 of the Act.

(c) *Scope.* Medical assistance included in paragraph (b) of this section is coverage of the Part A premium.

CMS-4199-P

Dated: _____

Xavier Becerra,

Secretary,

Department of Health and Human Services.