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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR parts 403, 409, 410, 411, 414, 415, 416, 418, 424, 425, 489, and 498

[CMS-1715-F and IFC]

RIN 0938-AT72

Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations Final Rule; and Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine Interim Final Rule

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule and interim final rule.

SUMMARY: This major final rule addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program quality reporting requirements; Medicaid Promoting Interoperability Program requirements for eligible professionals; the establishment of an ambulance data collection system; updates to the Quality Payment Program; Medicare enrollment of Opioid Treatment Programs and enhancements to provider enrollment regulations

Pierre Yong, (410) 786-8896, or Lindsey Baldwin, (410) 786-1694, for issues related to Medicare coverage of opioid use disorder treatment services furnished by opioid treatment programs (OTPs).

Lindsey Baldwin, (410) 786-1694, for issues related to bundled payments under the PFS for substance use disorders.

Emily Yoder, (410) 786-1804, or Christiane LaBonte, (410) 786-7237, for issues related to the comment solicitation on opportunities for bundled payments under the PFS.

Regina Walker-Wren, (410) 786-9160, for issues related to physician supervision for physician assistant (PA) services and review and verification of medical record documentation.

Ann Marshall, (410) 786-3059, Emily Yoder, (410) 786-1804, Liane Grayson, (410) 786-6583, or Christiane LaBonte (410) 786-7237, for issues related to care management services.

Terry Simananda, (410) 786-8144, for issues related to interim final rule with comment period (payment for self-administered esketamine).

Kathy Bryant, (410) 786-3448, for issues related to coinsurance for colorectal cancer screening tests and global surgery data collection.

Pamela West, (410) 786-2302, for issues related to therapy services.

Ann Marshall, (410) 786-3059, Emily Yoder, (410) 786-1804, or Christiane LaBonte, (410) 786-7237, for issues related to payment for evaluation and management services.

Thomas Kessler (410) 786-1991, for issues related to ambulance physician certification statement.

Felicia Eggleston (410) 786-9287 or Amy Gruber, (410) 786-1542, for issues related to the ambulance fee schedule and the requirements related to the Medicare ground ambulance data collection system.

services, as well as changes in the statute. This final rule also includes discussions and provisions regarding several other Medicare Part B payment policies, Medicare Shared Savings Program quality reporting requirements, Medicaid Promoting Interoperability Program requirements for eligible professionals, the establishment of a ground ambulance data collection system, updates to the Quality Payment Program, Medicare enrollment of Opioid Treatment Programs and enhancements to provider enrollment regulations concerning improper prescribing and patient harm; and amendments to Physician Self-Referral Law advisory opinion regulations. Specifically, this final rule addresses:

- Practice Expense RVUs (section II.B.)
- Malpractice RVUs (section II.C.)
- Geographic Practice Cost Indices (GPCIs) (section II.D.)
- Potentially Misvalued Services under the PFS (section II.E.)
- Telehealth Services (section II.F.)
- Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid

Treatment Programs (section II.G.)

- Bundled Payments Under the PFS for Substance Use Disorders (section II.H.)
- Physician Supervision for Physician Assistant (PA) Services (section II.I.)
- Review and Verification of Medical Record Documentation (section II.J.)
- Care Management Services (section II.K.)
- Coinsurance for Colorectal Cancer Screening Tests (section II.L.)
- Therapy Services (section II.M.)
- Valuation of Specific Codes (section II.N.)

- Comment Solicitation on Opportunities for Bundled Payments under the PFS (section II.O.)

- Payment for Evaluation and Management (E/M) Services (section II.P.)

- Ambulance Coverage Services–Physician Certification Statement (section III.A.)

- Ambulance Fee Schedule–Medicare Ground Ambulance Data Collection System (section III.B.)

- Intensive Cardiac Rehabilitation (section III.C.)

- Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs) (section III.D.)

- Medicare Shared Savings Program Quality Measures (section III.E.)

- Open Payments (section III.F.)

- Home Infusion Therapy Benefit (section III.G.)

- Medicare Enrollment of Opioid Treatment Programs and Enhancements to Existing General Enrollment Policies Related to Improper Prescribing and Patient Harm (section III.H.)

- Deferring to State Scope of Practice Requirements (section III.I.)

- Advisory Opinions on the Application of the Physician Self-Referral Law (section III.J.)

- Updates to the Quality Payment Program (section III.K.)

- Physician Self-Referral Law: Annual Update to the List of CPT/HCPCS Codes (section IV.)

- Interim Final Rule with Comment Period: Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine (HCPCS codes G2082 and G2083) (section V.)

Response: We agree with the need for significant outreach to OTP providers regarding coordination of benefits, and are collaborating with SAMHSA – which certifies OTP providers – to do so. We will explore options around providing technical assistance on connecting eligible clients to Medicare and Medicaid coverage.

Comment: One commenter suggested that as part of supporting the transition from Medicaid to Medicare coverage of OTP services, CMS issue guidance to remind states to continue transportation coverage for full benefit dually eligible individuals receiving services under the Medicare OTP benefit.

Response: As noted elsewhere, Medicare is the primary payer for services that are payable by both Medicare and Medicaid. However, Medicare has a limited non-emergency ambulance transportation benefit. If a full benefit dually eligible individual is obtaining a Medicaid-coverable benefit for which Medicare is the primary payer, the state must assure, in certain circumstances, transportation to the medical service (in the limited instances in which Medicaid does not cover a service Medicare covers, it is optional for states to cover transportation). As a result, when states cover OTP services, and when the applicable criteria are met, Medicaid must assure non-emergency medical transportation for full benefit dually eligible individuals obtaining Medicare-covered OTP services.

Comment: Several commenters supported the proposal to initially set the copayment for OTP services zero, but requested that this policy be made permanent for dually eligible individuals.

Response: We will consider issues on future copayment rates, and on keeping the zero copayment for dually eligible individuals, as part of any future rulemaking on the cost-sharing requirements for the benefit as a whole.

III. Other Provisions of the Proposed Regulations

A. Changes to the Ambulance Physician Certification Statement Requirement

Under our ongoing initiative to identify Medicare regulations that are unnecessary, obsolete, or excessively burdensome on health care providers and suppliers, we proposed to revise §§ 410.40 and 410.41. Importantly, in the proposed rule (84 FR 40680), we first clarified that these requirements apply to ambulance providers, as well as suppliers. We stated that the revisions would give certain clarity to ambulance providers and suppliers regarding the physician or non-physician certification statement and add staff who may sign certification statements when the ambulance provider or supplier is unable to obtain a signed statement from the attending physician.

1. Exceptions to Certification Statement Requirement

Under section 1861(s)(7) of the Act, ambulance services are covered where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Currently, § 410.40(d) specifies the medical necessity requirements for both nonemergency, scheduled, repetitive ambulance services and nonemergency ambulance services that are either unscheduled or that are scheduled on a non-repetitive basis. In the final rule with comment period that appeared in the January 25, 1999 **Federal Register** (64 FR 3637) (hereinafter referred to as the "January 25, 1999 final rule with comment period"), we stated that a physician certification statement (PCS) must be obtained as evidence that the attending physician has determined that other means of transportation are contraindicated and that the transport is medically necessary (64 FR 3639). In the final rule with comment period that appeared in the February 27, 2002 **Federal Register** (67 FR 9100) (hereinafter referred to as the "February 27, 2002 final rule with comment period"), we added

that a certification statement (hereinafter referred to as “non-physician certification statement”) could be obtained from other authorized staff should the attending physician be unavailable. (67 FR 9111)

We stated in the proposed rule (84 FR 40680) that currently there are no circumstances, other than those specified at § 410.40(d)(3)(ii) and (iv), granting exceptions to the need for a PCS or non-physician certification statement, and that we have received feedback from ambulance providers, suppliers, and their industry representatives (“stakeholders”) that various situations exist where the need for a PCS or non-physician certification is excessive, or at least redundant to similar existing documentation requirements. Two of the most prominent circumstances identified by the stakeholders include interfacility transports (IFTs), commonly referred to as hospital-to-hospital transports, and specialty care transports (SCTs), and stakeholders have requested that we incorporate additional exceptions into the regulatory framework.

As we discussed in the proposed rule (84 FR 40680 through 40681), upon reviewing the need for a PCS and non-physician certification statement, stakeholders’ concerns, and our commitment to reducing the burden placed on providers and suppliers, we have determined that instead of incorporating additional exceptions, our efforts would be better served by minorly altering the structure of the existing regulatory framework. We stated in the proposed rule that these changes are intended to maximize flexibility for ambulance providers and suppliers to obtain the requisite certification statements and maintain the focus on the determination that other means of transportation are contraindicated and that the transport is medically necessary.

To accomplish this, we proposed to add a new paragraph (a) in § 410.40 in which we would define both PCSs, as well as non-physician certification statements. Therefore, we

proposed to redesignate existing paragraph (a) “Basic rules” as paragraph (b) and redesignate the remaining paragraphs, respectively. Most significantly, paragraph (d) “Medical necessity requirements” will be redesignated as paragraph (e).

We stated in the proposed rule (84 FR 40681) that for paragraph (a), the two definitions, PCSs and non-physician certification statements, would clarify that: (1) the focus is on the certification of the medical necessity provisions contained in newly redesignated paragraph (e)(1); and (2) the form of the certification statement is not prescribed, thus affording maximum flexibility to ambulance providers and suppliers. We stated that since the two definitions would incorporate the requirement to obtain a certification of medical necessity, we proposed a conforming change to newly redesignated paragraph (e)(2) to remove the language requiring that an order certifying medical necessity be obtained.

As we stated in the proposed rule, we have repeatedly been told by stakeholders that there are ample opportunities for ambulance providers and suppliers to convey the information required in the certification statement. Stakeholders have mentioned, for example, that for transports such as IFTs and SCTs other requirements of federal, state, or local law require them to obtain other documentation, such as Emergency Medical Treatment & Labor Act (EMTALA) forms and medical transport forms, that serve the same purpose as the PCS or non-physician certification statement. There is every likelihood that other ambulance transports require similarly styled documentation that likewise could serve the same purpose.

To be clear, our regulations have never prescribed the precise form or format of this required documentation. As we discussed in the proposed rule, to satisfy the requirements of section 1861(s)(7) of the Act, ambulance providers’ and suppliers’ focus should be on clearly documenting the threshold determination that other means of transportation are contraindicated

and that the transport is medically necessary. We stated that the precise form or format by which that information is conveyed has never been prescribed. We further stated that our aim here is to ensure that ambulance providers and suppliers understand they have flexibility in the form by which they convey the requirements of proposed § 410.40(e), so long as that threshold determination is clearly expressed.

We stated in the proposed rule that the definition of non-physician certification statement in § 410.40(a) would incorporate the existing requirements that apply when an ambulance provider or supplier is unable to obtain a signed PCS from the attending physician and, instead, obtains a non-physician certification statement, including: (1) that the staff have personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished; (2) the employment-related requirements; and (3) the specific staff that can sign in lieu of the attending physician. We stated that included within the definition of non-physician certification statement, and as further discussed below, is an expansion of the list of staff who may sign when the attending physician is unavailable. In light of the staff being listed as part of the definition of non-physician certification statement at § 410.40(a), we proposed a corresponding change to proposed and newly redesignated paragraph (e)(3)(iii) to remove the reference to the staff currently listed within the paragraph. Moreover, in paragraphs (e)(3)(i) and (iv), we proposed changes to refer to the newly redesignated paragraph (e), and in paragraph (e)(3)(v), we proposed changes to refer to the newly defined terms in paragraph (a), specifically the physician or non-physician certification statement. Lastly, we also proposed a corresponding change to § 410.41(c)(1) to add that ambulance providers or suppliers must indicate on the claims form that, "when applicable, a physician certification statement or non-physician certification statement is on file."

In the CY 2013 PFS final rule with comment period (77 FR 69161), we stated that the Secretary is the final arbiter of whether a service is medically necessary for Medicare coverage. We stated in the proposed rule that we believe that the proposed changes would better enable contractors to establish the medical necessity of these transports by focusing more on the threshold medical necessity determination as opposed to the form or format of the documentation used. We further stated that we did not anticipate that this clarification will alter the frequency of claim denials.

In 2018, 68.9 percent of improper payments in non-emergency transport was due to insufficient documentation. Although we know the ambulance certification statement is a source of documentation error, we are unable to determine if clarifying that there is no specific form or format for the certification statement will lead to significantly fewer denials. Similarly, we are unable to determine whether adding to the list of non-physicians that may sign a certification statement will lead to significantly fewer denials. The impact primarily will afford providers increased flexibility in completing the form. We believe that claims denied for technical documentation issues currently are likely appealed and overturned in the supplier/provider's favor if the ambulance transport was indeed medically necessary. Therefore, although we believe the clarifications could result in fewer claims being denied, it is unlikely to be a statistically significant change.

2. Addition of Staff Authorized to Sign Non-Physician Certification Statements

In the January 25, 1999 final rule with comment period (64 FR 3637), we finalized language at § 410.40 to require ambulance providers or suppliers, in the case of nonemergency unscheduled ambulance services (§ 410.40(d)(3)) to obtain a PCS. In that rule, we explained that: (1) nonemergency ambulance service is a Medicare service furnished to a beneficiary for

whom a physician is responsible, therefore, the physician is responsible for the medical necessity determination; and (2) the PCS will help to ensure that the claims submitted for ambulance services are reasonable and necessary, because other methods of transportation are contraindicated (64 FR 3641). We further stated that we believed the requirement would help to avoid Medicare payment for unnecessary ambulance services that are not medically necessary even though they may be desirable to beneficiaries. However, in that final rule with comment period, we also addressed the ability of ambulance providers or suppliers to obtain a written order from the beneficiary's attending physician within 48 hours after the transport to avoid unnecessary delays. We agreed with stakeholders that while it is reasonable to expect that an ambulance supplier could obtain a pretransport PCS for routine, scheduled trips, it is less reasonable to impose such a requirement on unscheduled transports, and that it was not necessary that the ambulance suppliers have the PCS in hand prior to furnishing the service. To avoid unnecessary delays for unscheduled transports, we finalized the requirement that required documentation can be obtained within 48 hours after the ambulance transportation service has been furnished.

In the February 27, 2002 final rule with comment period (67 FR 9111), we noted that we had been made aware of instances in which ambulance suppliers, despite having provided ambulance transports, were, through no fault of their own, experiencing difficulty in obtaining the necessary PCS within the required 48-hour timeframe. We stated that the 48-hour period remained the appropriate period of time, but created alternatives for ambulance providers and suppliers unable to obtain a PCS. We finalized an alternative at § 410.40(d)(3)(iii) where ambulance providers and suppliers unable to obtain a PCS from the attending physician could obtain a signed certification (not a physician certification statement) from certain other staff. At

that time, we identified several staff members, including a physician assistant (PA), nurse practitioner (NP), clinical nurse specialist (CNS), registered nurse (RN), and a discharge planner as staff members able to sign such a non-physician certification statement. The only additional constraints are: (1) that the staff be employed by the beneficiary's attending physician or by the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported; and (2) that the staff have personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished.

We stated in the proposed rule (84 FR 40682) that in the intervening years, we have received feedback from stakeholders that other staff, such as licensed practical nurses (LPNs), social workers, and case managers, should be included in the list of staff that can sign a certification statement. Similar to the currently designated staff, we stated that we now believe that LPNs, social workers, and case managers who have personal knowledge of a beneficiary's condition at the time ambulance transport is ordered and the service is furnished have a skill set largely equal or similar to the other staff members. Thus, we proposed as part of the new definition of non-physician certification statement at § 410.40(a)(2)(iii) to add LPNs, social workers, and case managers to the list of staff who may sign a certification statement when the ambulance provider or supplier is unable to obtain a signed PCS from the attending physician. As with the staff currently listed in § 410.40(d)(3)(iii), LPNs, social workers, and case managers would need to be employed by the beneficiary's attending physician or the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported, and have personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished. We also requested comments on whether other staff should be

included in this regulation, and requested that commenters identify such staff's licensure and position and the reason it would be appropriate for such staff to sign a certification statement.

The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our changes to the ambulance certification requirements, including the addition of licensed practical nurses, social workers, and case managers to the list of non-physician staff who are authorized to sign a certification statement when a statement cannot be obtained from the attending physician. One commenter noted that CMS should monitor the new provisions closely to ensure that enforcement is fair, consistent, and expected and the new approach is not abused.

Response: We agree that the new provisions must be fairly and consistently applied. Through our contractors, we will focus on ensuring a fair and consistent application of the new requirements so that the requirements are not subject to abuse.

Comment: One commenter recommended that a licensed non-physician staff member should be authorized to sign a certification statement for all emergency and nonemergency cases and that adding an additional layer of bureaucracy does not increase quality, but does increase cost.

Response: We do not currently require a certification statement for emergency ambulance transport, and did not propose to add such a requirement for emergency ambulance transport as it would, among other things, increase documentation burden and costs. We continue to believe that requiring a certification statement for non-emergency ambulance transports is necessary. Of note, the certification assists our efforts in combating fraud, waste and abuse.

Comment: One commenter supported the “proposal to eliminate the PCS as a requirement for hospital-to-hospital transports,” and requested confirmation that CMS will not burden ambulance service providers and suppliers with having to obtain the other documents, for example, transfer forms and/or EMTALA forms, that can be used in lieu of the PCS and to clarify that if a PCS is not required for interfacility transports, then ambulance service providers and suppliers will not be required to obtain a certificate of mailing (or proof of mailing).

Response: To be clear, we did not propose the elimination of the PCS as a requirement for hospital-to-hospital transports. Rather, we clarified that the precise form or format of the certification statement is not prescribed, thus increasing ambulance suppliers’ and providers’ flexibility to comply with the certification statement requirements. Also, the steps we have taken to clarify the regulations do not obviate a provider’s or supplier’s responsibility to submit required documentation upon request to Medicare review contractors, which may request documentation from the supplier or provider to evaluate eligibility, coverage, medical necessity, and other reimbursement-related factors.

Comment: One commenter questioned if CMS would consider the completion of a non-physician certification statement by nursing staff in the emergency department as compliant with the regulatory requirements, if the treating physician is unavailable due to treatment of another patient in the Emergency Department.

Response: The scope of this rule is to clarify the requirements associated with the form and content of the physician certification statement and the non-physician certification statement along with adding additional staff members who may, under the appropriate circumstances, sign a non-physician certification statement. Although this scenario could be acceptable should the

criteria set forth in the regulations be met, specific fact-based scenarios should be discussed with the appropriate Medicare Administrative Contractor.

Comment: One commenter recommended CMS make additional changes, including modernizing and streamlining the 855B Ambulance Enrollment form, eliminating the duplicative requirements for patient signatures, and modernizing the revocation process for suppliers' and providers' ability to bill Medicare.

Response: These recommendations are outside the scope of the proposed changes.

Comment: One commenter noted that the changes will do very little to lessen the unnecessary burden that the PCS requirement imposes on ambulance providers and suppliers every day and that CMS, instead, should "eliminate this useless exercise in chasing paper" and alleged that the PCS carries "no weight." This same commenter recommended that CMS add several additional staff members who can sign the non-physician certification statement, including licensed vocational nurses (LVNs), advanced practice registered nurses (APRNs), paramedics not functioning as an employee of the ambulance provider or supplier furnishing the ambulance services for which payment is claimed, physical therapists, occupational therapists, psychiatrists and psychologists.

Response: Although we understand the commenter's concern regarding burden, we disagree that the certification statements are a useless exercise or that they carry no weight. We specifically noted within the proposed rule that the changes were intended to maximize flexibility for ambulance providers and suppliers to obtain the requisite certification statements and maintain the focus on the determination that other means of transportation are contraindicated and that the transport is medically necessary. We believe the clarifications are in line with our intended outcome and the certification statements serve an important role in

B. Establishment of a Medicare Ground Ambulance Data Collection System

1. Background

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Since April 1, 2002, payment for ambulance services has been made under the ambulance fee schedule (AFS), which the Secretary established under section 1834(l) of the Act. Payment for an ambulance service is made at the lesser of the actual billed amount or the AFS amount, which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a GAF, and other applicable adjustment factors as set forth at section 1834(l) of the Act and § 414.610 of the regulations. In accordance with section 1834(l)(3) of the Act and § 414.610(f), the AFS rates are adjusted annually based on an inflation factor. The AFS also incorporates two permanent add-on payments and three temporary add-on payments to the base rate and/or mileage rate. The two permanent add-on payments are: (1) a 50 percent increase in the standard mileage rate for ground ambulance transports that originate in rural areas where the travel distance is between 1 and 17 miles; and (2) a 50 percent increase to both the base and mileage rate for rural air ambulance transports. The three temporary add-on payments are: (1) a 3 percent increase to the base and mileage rate for ground ambulance transports that originate in rural areas; (2) a 2 percent increase to the base and mileage rate for ground ambulance transports that originate in urban areas; and (3) a 22.6 percent increase in the base rate for ground ambulance transports that originate in "super rural" areas. Our regulations relating to coverage of and payment for ambulance services are set forth at 42 CFR part 410, subpart B, and 42 CFR part 414, subpart H.

2. Statutory Requirement for Ground Ambulance Providers and Suppliers to Submit Cost and Other Information

Section 50203(b) of the BBA of 2018 added a new paragraph (17) to section 1834(l) of the Act, which requires ground ambulance providers of services and suppliers to submit cost and other information. Specifically, section 1834(l)(17)(A) of the Act requires the Secretary to develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary for providers and suppliers of ground ambulance services. Such system must be designed to collect information: (1) needed to evaluate the extent to which reported costs relate to payment rates under the AFS; (2) on the utilization of capital equipment and ambulance capacity, including information consistent with the type of information described in section 1121(a) of the Act; and (3) on different types of ground ambulance services furnished in different geographic locations, including rural areas and low population density areas described in section 1834(l)(12) of the Act (super rural areas).

Section 1834(l)(17)(B)(i) of the Act requires the Secretary to specify the data collection system by December 31, 2019, and to identify the ground ambulance providers and suppliers that would be required to submit information under the data collection system, including the representative sample defined at clause (ii).

Under section 1834(l)(17)(B)(ii) of the Act, not later than December 31, 2019, for the data collection for the first year and for each subsequent year through 2024, the Secretary must determine a representative sample to submit information under the data collection system. The sample must be representative of different types of ground ambulance providers and suppliers (such as those providers and suppliers that are part of an emergency service or part of a

government organization) and the geographic locations in which ground ambulance services are furnished (such as urban, rural, and low population density areas), and not include an individual ground ambulance provider or supplier in the sample for 2 consecutive years, to the extent practicable.

Section 1834(l)(17)(C) of the Act requires that for each year, a ground ambulance provider or supplier identified by the Secretary in the representative sample as being required to submit information under the data collection system for a period for the year must submit to the Secretary the information specified under the system in a form and manner, and at a time specified by the Secretary.

Section 1834(l)(17)(D) of the Act requires that beginning January 1, 2022, the Secretary apply a 10 percent payment reduction to payments made under section 1834(l) of the Act for the applicable period to a ground ambulance provider or supplier that is required to submit information under the data collection system and does not sufficiently submit such information. The term “applicable period” is defined under section 1834(l)(17)(D)(ii) of the Act to mean, for a ground ambulance provider or supplier, a year specified by the Secretary not more than 2 years after the end of the period for which the Secretary has made a determination that the ground ambulance provider or supplier has failed to sufficiently submit information under the data collection system. A hardship exemption to the payment reduction is authorized under section 1834(l)(17)(D)(iii) of the Act, which provides that the Secretary may exempt a ground ambulance provider or supplier from the payment reduction for an applicable period in the event of significant hardship, such as a natural disaster, bankruptcy, or other similar situation that the Secretary determines interfered with the ability of the ground ambulance provider or supplier to submit such information in a timely manner for the specified period. Lastly, section

1834(l)(17)(D)(iv) of the Act requires the Secretary to establish an informal review process under which a ground ambulance provider or supplier may seek an informal review of a determination that the provider or supplier is subject to the payment reduction.

Section 1834(l)(17)(E)(i) of the Act allows the Secretary to revise the data collection system as appropriate and, if available, taking into consideration the report (or reports) that the Medicare Payment Advisory Commission (MedPAC) will submit to Congress. Section 1834(l)(17)(E)(ii) of the Act specifies that, to continue to evaluate the extent to which reported costs relate to payment rates under section 1834(l) of the Act and other purposes as the Secretary deems appropriate, the Secretary shall require ground ambulance providers and suppliers to submit information for years after 2024, but in no case less often than once every 3 years, as determined appropriate by the Secretary.

As required by section 1834(l)(17)(F) of the Act, not later than March 15, 2023, and as determined necessary by MedPAC, MedPAC must assess, and submit to Congress a report on, information submitted by providers and suppliers of ground ambulance services through the data collection system, the adequacy of payments for ground ambulance services and geographic variations in the cost of furnishing such services. The report must contain the following:

- An analysis of information submitted through the data collection system;
- An analysis of any burden on ground ambulance providers and suppliers associated with the data collection system;
- A recommendation as to whether information should continue to be submitted through such data collection system or if such system should be revised by the Secretary, as provided under section 1834(l)(17)(E)(i) of the Act; and
- Other information determined appropriate by MedPAC.

Section 1834(l)(17)(G) of the Act requires the Secretary to post information on the results of the data collection on the CMS website, as determined appropriate by the Secretary.

Section 1834(l)(17)(H) of the Act requires the Secretary to implement the provisions of section 1834(l)(17) of the Act through notice and comment rulemaking.

Section 1834(l)(17)(I) of the Act provides that the Paperwork Reduction Act (Title 44, Chapter 35 of the U.S. Code) does not apply to collection of information required under section 1834(l)(17) of the Act.

Section 1834(l)(17)(J) of the Act provides that there shall be no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the data collection system or identification of respondents.

We note that while the requirements of section 1834(l)(17) of the Act are specific to ground ambulance organizations, many stakeholders have expressed interest to us in making this type of information available for other providers and suppliers of ambulance services. For example, air ambulance organizations have suggested they are interested in making this information available. We recognize that the regulation of air ambulances spans multiple federal agencies, and note that section 418 of the FAA Reauthorization Act of 2018 (Pub. L. 115-254, enacted October 5, 2018) requires the Secretary of Transportation , in consultation with the Secretary of HHS, to establish an advisory committee that includes HHS; DOT; insurance regulators; patient and consumer advocacy groups; physicians specializing in emergency, trauma, cardiac, or stroke; various segments of the air ambulance industry; and others. This committee will review options to improve the disclosure of charges and fees for air medical services, better inform consumers of insurance options for those services, and better inform and protect consumers of these services. We welcomed comments on the state of the air ambulance

industry and how CMS can work within its statutory authority to ensure that appropriate payments are made to air ambulance organizations serving the Medicare population.

We received 58 public comments on our proposals to establish a ground ambulance data collection system, including 11 public comments on air ambulance payments from air ambulance organizations, air and ground ambulance organizations, an international trade association that represents providers of emergency air medical services and critical care ground medical transport services, an insurance company and a national heart association. The following is a summary of the comments we received and our response.

Comments: Many commenters stated that they appreciate that CMS proposed to establish a data collection system for ground ambulance providers and suppliers, but noted that ground ambulance transportation is only a part of the overall emergency medical services ecosystem. Some commenters described the vital role of air medical services in providing timely critical care responses to high-acuity life-or-death incidents, and stated that air medical service providers and suppliers are the critical link to tertiary care in severe medical emergencies.

Several commenters stated that the current payment rates for air ambulance services are inadequate and that, except for the annual ambulance inflation factor (AIF), CMS has not adjusted the AFS since it was established in 2002. They stated that prior to 2006, CMS had exercised its authority to make periodic adjustments to the AFS based on the actual costs of providing air medical transportation, and that Medicare payments have failed to keep pace with costs of providing air medical services. One commenter stated that ensuring that Medicare beneficiaries continue to have access to air medical transportation when they need it the most should be a priority for the Medicare program, and another commenter suggested that the Medical or Transportation Consumer Price Index (CPI) should be used to update air ambulance

payments. Other commenters noted that the Medicare payment rate has an impact on Medicaid payment rates, as well as payment rates from private payors. Commenters described the various factors that are increasing the cost of providing air medical services, particularly in rural areas.

According to several commenters, air ambulance providers and suppliers have access to detailed cost information and are willing to share this information with CMS. Several stated that there is an existing study entitled “Air Medical Services Cost Study Report” (March 24, 2017; Xcenda) that provides accurate information on the costs of providing air ambulance services, and that this study could be used to determine appropriate payment for air ambulance providers and suppliers under the Medicare program.

Some commenters encouraged CMS to continue to explore ways to collect the same cost, revenue, and utilization data from air ambulance providers and suppliers that it has proposed to collect from ground ambulance providers and suppliers. Some commenters stated that ground and air ambulance services are increasingly contributing to growing healthcare expenditures and that they appreciate CMS’ efforts to better understand the associated services and costs.

Several commenters urged CMS to exercise its existing authority to develop, with stakeholder input, a data collection process that would provide CMS with current cost data that could be used to rebase the AFS. The commenters also stated that this would result in more adequate Medicare payment rates for air ambulance services, and that this would also address inadequate payment from commercial insurers.

Response: We agree that it is essential that Medicare beneficiaries have adequate access to ambulance services, especially in rural areas, and we appreciate the comments regarding the adequacy of the Medicare air ambulance rates and the suggestions regarding updating those rates. We note that section 1834(l)(17) of the Act, which is the authority for establishing a

ground ambulance services data collection system, applies only to providers and suppliers of ground ambulance services. Accordingly, we do not have the statutory authority to implement a data collection system for air ambulance services at this time.

3. Research to Inform the Development of a Ground Ambulance Data Collection System

To inform the development of a ground ambulance data collection system, including a representative sampling plan, our contractor developed recommendations regarding the methodology for collecting cost, revenue, utilization and other information from ground ambulance providers and suppliers (also collectively referred to in this final rule as “ground ambulance organizations”) and a sampling plan consistent with sections 1834(l)(17)(A) and (B) of the Act. Our contractor also developed recommendations for the collection and reporting of data with the least amount of burden possible to ground ambulance organizations. The recommendations took into consideration the following:

- An environmental scan consisting of a review of existing peer-reviewed literature, government and association reports, and targeted web searches. The purpose of the environmental scan was to collect information on costs and revenues of ground ambulance transportation services, identify background information regarding the differences among ground ambulance organizations including state and local requirements that may impact the costs of providing ambulance services, and describe financial challenges facing the ambulance industry. Five previously fielded ambulance cost collection tools were also identified and analyzed and are described below.

- Interviews with ambulance providers and suppliers, billing companies, and other stakeholders to determine all major cost, revenue, and utilization components, and differences in these components across ground ambulance organizations. These discussions provided valuable

information on the process for developing a data collection system, including how to best elicit valid responses and limit burden on respondents, as well as the timing of the data collection.

- Analyses of Medicare claims and enrollment data, including all fee-for-service (FFS) Medicare claims with dates of service in 2016, the most recent complete year of claims data for ground ambulance services.

Our contractor also analyzed the following five data collection tools that currently collect or have collected data from ground ambulance organizations:

- The Moran Company Statistical and Financial Data Survey (the “Moran survey”).⁸⁸ In 2012, American Ambulance Association (AAA) commissioned a study with the goal of developing a data collection tool and making recommendations for collecting data to determine the costs of delivering ground ambulance services to Medicare beneficiaries. The result was the Moran survey, which is a two-step data collection method in which all ambulance providers and suppliers first complete a short survey with basic descriptive information on their characteristics, and second, a representative sample of ambulance providers and suppliers report more specific cost information.

- Ground Emergency Medical Transportation (GEMT) Cost Report form and instructions from California’s Medicaid program.⁸⁹ The GEMT Cost Report form and instructions is used by some states to determine whether ambulance providers and suppliers should receive supplemental payments from state Medicaid programs to cover shortfalls between

⁸⁸ The Moran Company (2014). Detailing “Hybrid Data Collection Method” for the Ambulance Industry: Beta Test Results of the Statistical & Financial Data Survey & Recommendations, [Online]. Available at <https://s3.amazonaws.com/americanambulance-advocacy/AAA+Final+Report+Detailing+Hybrid+Data+Collection+Method.pdf>.

⁸⁹ State of California – Health and Human Services Agency Department of Health Care Services Ground Emergency Medical Transportation (2013). Ground Emergency Medical Transportation Services Cost Report General Instructions for Completing Cost Report Forms, [Online]. Available at http://www.dhcs.ca.gov/provgovpart/documents/gemt/gemt_cstrptinstr.pdf.

revenue and costs. This data collection tool is geared toward government entities, as private ambulance providers and suppliers do not qualify for the supplemental payments.

- The Emergency Medical Services Cost Analysis Project (EMSCAP) framework.⁹⁰

The National Highway Traffic Safety Administration funded EMSCAP in 2007 to develop a framework for determining the cost for an EMS system at the community level. Subsequently, EMSCAP researchers used this framework to develop a cost workbook and pilot test the tool on three communities representing rural, urban, and suburban areas. EMS services within the three communities included volunteer, paid, and combination EMS agencies, both fire department and third service-based. Third service-based refers to services provided by a local government that include a fire department, police department and a separate EMS, forming an emergency trio.

- A 2012 Government Accountability Office (GAO) ambulance survey.⁹¹ To examine ground ambulance suppliers' costs for transports, in 2012 GAO administered a web-based survey to a random sample of 294 eligible ambulance suppliers. GAO collected data on their 2010 costs, revenues, transports, and organizational characteristics. Although the GAO survey collected data for each domain at the summary level, it also prompted respondents to take into account multiple factors when calculating their summary costs.

- The Rural Ambulance Service Budget Model.⁹² This tool was developed by a task force of the Rural EMS and Trauma Technical Assistance Center with funds from the Health Resources and Services Administration (HRSA) in the early 2000s. The purpose was to provide assistance to rural ambulance entities in establishing an annual budget and to calculate the value

⁹⁰ Lerner, E. B., Nichol, G., Spaite, D. W., Garrison, H. G., & Maio, R. F. (2007). A comprehensive framework for determining the cost of an emergency medical services system. Available at <https://www.mcw.edu/departments/emergency-medicine/research/emergency-medical-services-cost-analysis-project>.

⁹¹ U.S. Government Accountability Office (2012). Survey of Ambulance Services. Available at <https://www.gao.gov/assets/650/649018.pdf>.

⁹² Health Resources and Services Administration. The Rural Ambulance Service Budget Model, [Online]. Available at <https://www.ruralcenter.org/resource-library/rural-ambulance-service-budget-model>.

of services donated by other entities, as well as services donated by the ambulance entity's staff to the community. The tool was last updated in 2010 and has been cited as a resource for rural ground ambulance organizations by state and national government agencies. However, use of the tool is not required by any of these agencies.

As discussed in the proposed rule, our contractor's analysis of these tools revealed that while there was overlap of the broad cost categories collected (for example, labor, vehicles, and facilities costs) via these tools, there were significant differences in the more specific data collected within these broad categories. Overall, there was a large amount of variability regarding whether the tools allowed for detailed accounting of costs and whether the tools used respondent-defined or survey-defined categories for reporting. The five tools also differed in terms of their instructions, format, and design in terms of how a portion of organizations' total costs were allocated to ground ambulance costs, the timeframe for reporting, and the flexibility of reporting.

Based on these activities, our contractor prepared a report entitled, "Medicare Ground Ambulance Data Collection System –Sampling and Data Collection Instrument Considerations and Recommendations" (referred to as "the CAMH⁹³ report") which is referenced throughout this final rule. It is available at <https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html> and provides more detail on the research, findings and recommendations concerning the data collection instrument and sampling.

We received comments on our research, including testing, to inform the data collection system. The following is a summary of the comments we received and our responses.

Comment: While commenters were generally very supportive of the proposed data collection system, several commenters stated that testing is a critical step in the development of

⁹³ CMS Alliance to Modernize Healthcare.

any survey and they were disappointed that we did not test the data collection instrument and sampling methodology prior to making our proposals. To address these concerns, the commenters recommended that CMS assess the quality and consistency of submitted data throughout the first year of data reporting, and consider revisions to the data collection instrument either during or after the first year of data collection to address any issues that are identified. They also asked that CMS work with stakeholders to provide any needed clarifications for subsequent collection years and make any adjustments necessary to assure that a statistically appropriate representative sample is obtained. A commenter recommended that CMS not wait for rulemaking cycles to clarify definitions or make other minor changes to the system, and that doing so would slow down the process and make the first years of data less useful. Many commenters urged CMS to provide substantial education to ground ambulance organizations and develop definitions and instruction manuals to ensure that accurate and usable data is obtained from all types of services as quickly as possible.

Response: While the data collection system and instrument was not widely tested prior to making our proposals, we conducted an extensive environmental scan as described above, consulted with as many stakeholders as possible throughout the tight timeframe between when the law was enacted and the statutory deadline for specifying the data collection system. This included meeting with all the major associations representing ground ambulance providers and suppliers, and conducting interviews with randomly selected ground ambulance organizations as described in our contractor's report. Given the extensive effort that has gone into preparing the data collection instrument and sampling plan, as well as the overall positive feedback we received from commenters to the proposed rule, we believe the data collection instrument and sampling plan will achieve the requirements of the statute. We also plan to conduct extensive

stakeholder outreach and develop educational materials to help respondents report accurate information, and will make revisions to the data collection instrument and sampling plan as expeditiously as possible to address any issues that are identified.

4. Final Policies for the Data Collection Instrument

a. Format

In the proposed rule, we discussed several options we considered for collecting the data including a survey, a cost report spreadsheet similar to the GEMT, and the Medicare Cost Report (MCR). During interviews with ambulance providers and suppliers, some participants stated that they would prefer that data collection be done through a cost report spreadsheet, rather than a survey, such as the GEMT and other similar data collection tools utilized by state Medicaid programs. They noted that data cost collection spreadsheets such as the GEMT are used in some states where supplemental payments are made to ground ambulance organizations based on costs and revenue reported via a cost reporting template. Although these tools are valuable to the ambulance suppliers that utilize them for Medicaid payment purposes, we noted that only a small number of states make use of these tools for the purpose of providing supplemental payments and that they are generally geared toward government run entities that provide a broad range of emergency medical services and not just ground ambulance services. We stated that for these reasons, we did not believe that these tools could be used by all ground ambulance organizations for Medicare payment purposes without significant revision.

During stakeholder outreach, other ambulance providers and suppliers stated their preference for survey-based reporting such as the Moran survey, because they believe survey reporting is less burdensome and allows more flexibility for reporting. We agreed that survey reporting can be designed to provide greater flexibility of reporting with reduced reporting

burden. However, the Moran survey recommended excluding small ground ambulance organizations with limited capacity or those which relied heavily on volunteer services, which we stated would exclude a large percentage of ground ambulance organizations from our sample, would not take into account the unique differences of government run ground ambulance entities, and could not be used by all ground ambulance organizations without significant revisions. Some ambulance organizations that favored using the Moran survey also recommended using cost reporting guidelines that are similar to the CMS requirements for the MCR. In the proposed rule, we stated that although we agree that standardization is important for data analysis, many smaller ground ambulance organizations have stated they would have difficulty complying with complex cost reporting guidelines. We stated that we believed that requiring ground ambulance organizations to complete and submit an MCR for the purpose of the data collection required in section 1834(l)(17) of the Act would be unnecessarily resource intensive and burdensome.

In the proposed rule, we also considered using multiple instruments or staged data collection as recommended in the Moran Report, where we would first collect organizational characteristic data from all ground ambulance organizations, use that information for sampling purposes, and then collect cost and revenue information from a sample of ambulance providers and suppliers. Using this approach, we stated we would need 100 percent participation from all ground ambulance organizations in reporting the organizational characteristic data in order for the data to be used for sampling purposes. We did not propose this approach because we believed multiple data collections would increase respondent burden and may not align with sections 1834(l)(17)(A) and (B) of the Act which requires CMS to collect data from a random sample and prohibits data collection from the same ground ambulance organizations in 2 consecutive years to the extent practicable.

In the proposed rule, we stated that we did not believe that any of the existing or previously used data collection instruments described above would be sufficient to adequately capture the data required by section 1834(l) of the Act. Therefore, we proposed to collect ground ambulance organization data using a survey that we developed specifically for this purpose, referred to as the data collection instrument, via a secure web-based system. We stated that we believed that the data collection instrument should be usable by all ground ambulance organizations, regardless of their size, scope of operations and services offered, and structure and proposed that the data collection instrument include screening questions and skip patterns that direct ground ambulance organizations to only view and respond to questions that apply to their specific type of organization. We stated that we also believed that the data collection instrument we proposed is easier to navigate and less time consuming to complete than a cost report spreadsheet. We also stated that the secure web-based survey would be available before the start of the first data reporting period to allow time for users to register, receive their secure login information, and receive training from CMS on how to use the system. Finally, we proposed to codify these policies at § 414.626.

We received comments on the format of the data collection instrument. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that they support our proposal to collect ground ambulance data using a survey developed specifically for this purpose and not use existing GEMT workbooks or Medicaid cost reports because they do not believe that either would provide the necessary information for CMS and MedPAC to use when addressing the questions that Congress set forth in the statute. They also expressed support for our approach to the development of a web-enabled data collection system and the principles that guided the

development of the data collection instrument. In particular, they noted our goal of developing a system that will balance respondent burden against the need to collect the data required by the statute, provide flexibility to collect data from diverse ambulance organizations, and enable the calculation of per-transport costs for comparison to Medicare payment rates. They encouraged us to collect the data in a manner that allows for as much analysis as possible, such as the comparison of per-transport costs across subgroups of ambulance organizations, and analyses estimating the marginal cost of a particular type of transport. These commenters stated that they believe the proposed data collection system and draft Medicare ground ambulance data collection instrument provide a solid foundation for future evaluation.

Some commenters stated that while they would have preferred a spreadsheet for the data collection instrument, they agree that the proposed web-based survey with skip logic and other embedded tools to help ground ambulance organizations navigate the data collection instrument will be helpful. They asked that CMS consider ways that web-based tools can leverage the technology to provide additional clarity around the data submission. For example, they stated that it may be useful to include standardized definitions or address common questions by incorporating links to specific questions to the terms/answers and to have definitions or allocation rules “pop-up” on the screen when a user starts a new question. One commenter requested that the data collection system allow enough time for the respondent to complete the information, to save partially completed data, and easily come back to where they left off to edit or continue entering the data. Commenters stated that they would welcome the chance to walk through the data collection system, as well as the data collection instrument once it is coded and share ideas about how the web-based nature of it can be refined. They would also like to work with CMS to find ways that may allow for easier data entry, including auto-population of certain

fields and an application programming interface (API) import method from commonly used accounting software.

While nearly all commenters expressed support for the proposed format of the data collection instrument, some commenters were concerned that due to the complexity of the data collection instrument, the response rate will be low and that the submitted data may be inaccurate, particularly for smaller ground ambulance organizations. One commenter recommended that low-volume ambulance organizations (for example, those providing 600 or fewer all-payer ground transports per year) should only be required to complete a much shorter version of the proposed data collection instrument in order to increase the response rate. This commenter suggested that for low-volume ambulance organizations, only the minimum information needed to calculate the organization's cost per transport, such as the organization's total annual budget, total number and type of transports regardless of payer, average number of miles per transport, type of organization, non-profit vs. for-profit status, use of shared space, and percent of labor hours from volunteers, should be collected.

Response: We thank the commenters for the overwhelming support of the proposed format of the data collection instrument and will implement many of the suggestions commenters provided to ensure the data collection system is user friendly and provides as many avenues for analysis as possible.

We understand the concern that upon first glance, the data collection instrument may appear complex, as well as the concern that it may suffer from a low response rate. However, we expect that ambulance organizations will find that the use of screening questions and skip patterns that direct them to only view and respond to questions that apply to their specific type of organization will be easier to navigate and less time consuming to complete than a cost report

spreadsheet. We believe that the data collection instrument will be usable by all ground ambulance organizations regardless of their size or other characteristics, and do not believe it is necessary or beneficial to have a limited data collection instrument for low-volume ambulance organizations to complete. Our belief is that all ground ambulance organizations that are chosen to participate in the sample will work with CMS and their ambulance associations to receive the assistance they need to report the data required, not just because they will receive a 10 percent payment reduction for failure to report the data, but also because they believe their data is important so that those analyzing the data can accurately assess whether or not Medicare payment rates are adequate. We specifically designed the data collection instrument to leave as many doors open as possible for data analysis while also considering the burden associated with every question.

Comment: Some commenters expressed concern that information on key organizational characteristics (such as organization type and use of volunteer labor) are being collected as part of this data collection effort, rather than in a separate data collection process that would occur before the collection of cost and revenue data. They stated this two-stage approach to data collection is needed to stratify the sample and ensure a representative sample.

Response: We recognize the desire that many commenters shared to have all of the organizational characteristic data prior to selecting samples to ensure that CMS has what commenters believe would be a complete set of data to use to stratify the sample. As stated in the proposed rule, we believe that Medicare claims and enrollment data provide CMS with enough data to appropriately stratify the sample. We also continue to believe that multiple data collections would increase respondent burden and that the commenters' suggestion to collect data from all ground ambulance organizations in the first data collection and then select a

random sample to collect data from some ground ambulance organizations in that same year or the year after may not align with sections 1834(l)(17)(B) of the Act, which requires CMS to collect data from a random sample and prohibits data collection from the same ground ambulance organizations in 2 consecutive years, to the extent practicable. Furthermore, we believe that collecting data on organizational characteristics as part of one data collection effort will enable skip patterns within the survey to limit the number of questions organizations with certain characteristics will need to answer.

After consideration of the comments, we are finalizing our proposal to collect ground ambulance organization data using a single survey-based data collection instrument delivered via a secure web-based system. We made a few technical changes to our proposals to codify these policies at § 414.626 including adding a definition for Medicare Ground Ambulance Data Collection Instrument. We are finalizing our proposals to codify these policies at § 414.626.

b. Scope of Cost, Revenue, and Utilization Data

Section 1834(l)(17)(A) of the Act requires CMS to develop a data collection system to collect data related to cost, revenue, utilization, and other information determined appropriate by the Secretary for ground ambulance organizations. Section 1834(1)(17)(A)(i) of the Act further specifies that the information collected through the system should be sufficient to evaluate the extent to which reported costs relate to payment rates.

In the proposed rule we stated that we considered several options regarding the scope of collecting data on ground ambulance cost, revenue, and utilization. One option was to require ground ambulance organizations to report on their: (1) total costs related to ground ambulance services; (2) total revenue from ground ambulance services; and (3) total ground ambulance service utilization. We stated that this approach considers all ground ambulance costs, revenue,

and utilization, regardless of whether the service was billable to Medicare or related to a Medicare beneficiary and that the advantage of this approach is that ground ambulance organizations already track information at their organizational level on total costs, revenue, and utilization for their own internal budgeting and planning. We stated that this method was also used to calculate an organization-level average cost per transport in two previous studies described below:

In a 2012 study entitled, “Ambulance Providers: Costs and Medicare Margins Varied Widely; Transports of Beneficiaries has Increased”⁹⁴, the GAO performed an analysis to assess how Medicare payments, including the temporary add-on payments, compared to costs reported using a survey. The GAO collected information via a survey on organizations’ total costs, including operating and capital costs, without restriction to costs associated with Medicare transports or costs incurred in responding to calls for service from Medicare beneficiaries. GAO then divided reported total costs by the reported number of transports (regardless of whether Medicare paid for the transport) to calculate an average cost per transport for each organization, and reported summary statistics across these averages, including a median cost per transport of \$429. However, to simplify data collection and analysis, the analysis was limited to ambulance suppliers that did not share operational costs with a fire department, hospital, or other entity. GAO stated that its calculations assumed that this average cost per transport was constant for all of an organization’s transports regardless of whether or not the patient transported was a Medicare beneficiary. This approach implicitly loads the costs associated with activities that did not result in a transport, such as responses by a ground ambulance where the patient could not be located, refused transport, or was treated on the scene, into the estimated cost per transport.

⁹⁴ This report is available at <https://www.gao.gov/assets/650/649018.pdf>.

The second study, “Report to Congress Evaluation of Hospitals’ Ambulance Data on Medicare Cost Reports and Feasibility of Obtaining Cost Data from All Ambulance Providers and Suppliers,”⁹⁵ was conducted by HHS as required under the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L 112-240, enacted January 2, 2013). This report used data from Medicare cost reports as its data source, rather than a survey, and included only ambulance providers, rather than ambulance providers and suppliers. It described substantially higher costs per transports for ambulance providers compared to the estimate from GAO, with a median of approximately \$1,750 per transport. It did not compare reported total costs to Medicare revenue tallied in claims data with and without the temporary add-on payments. Neither the GAO nor the HHS report compared costs and AFS payment rates for specific Healthcare Common Procedure Coding System (HCPCS) codes because the available cost data in both studies did not support that level of analysis.

Another option we discussed in the proposed rule was considering only those costs that are relevant to ground ambulance services furnished to Medicare beneficiaries. We stated that collecting costs associated with specific services (such as Medicare transports) and excluding other services (such as Medicaid transports or responses that did not result in transport) would require either a much more intensive and costly data collection approach (such as time and motion studies) or assumptions on which portions of total costs were related to the specific activity. We also stated that we believed this approach would be overly burdensome and complex for ground ambulance organizations, especially those who provide other services in addition to ground ambulance services.

⁹⁵ This report is available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/Downloads/Report-To-Congress-September-2015.pdf>.

A third option we considered for the proposed rule was to only consider those costs that are related to the specific ground ambulance transport services that are paid under the AFS. We stated that this would require ground ambulance organizations to report costs, revenue, and utilization related to specific levels of services reported with HCPCS codes, but not costs, revenue, and utilization for other services such as responses that did not result in a transport (which is not covered under the AFS). In the proposed rule we stated that we believe this option would be overly burdensome and complex.

We stated that in discussions with ambulance providers and suppliers, we were informed that ground ambulance organizations most often track organization-level total costs, revenue, and utilization across all activities and services furnished to all patients. We were told that most would find it difficult to report costs, revenue, and utilization associated with services furnished exclusively to Medicare beneficiaries or associated with Medicare services covered under the AFS.

Therefore, we proposed the first option, which would require ground ambulance organizations to report on their: (1) total costs related to ground ambulance services; (2) total revenue from ground ambulance services; and (3) total ground ambulance service utilization. We stated that this approach considers all ground ambulance costs, revenue, and utilization, regardless of whether the service was billable to Medicare or related to a Medicare beneficiary to collect total cost, total revenue, and total utilization data.

Although we proposed to collect a ground ambulance organization's total costs and total revenues, we stated we were aware that many ground ambulance organizations share operational costs with fire departments, other public service organizations, air ambulance services, hospitals, and other entities. We stated that for these organizations, only a portion of certain capital and

operational costs contribute to total ground ambulance costs, and only a portion of revenue is from ground ambulance services. We also stated we were aware that some ground ambulance suppliers deploy emergency medical technicians (EMTs) in fire trucks, which will make it difficult to determine whether the fire truck costs should be factored into the total ground ambulance costs, and if so, how that will be calculated.

In the proposed rule, we stated that one option to address these challenges is to limit data collection to ground ambulance organizations that do not share operational costs with fire departments, hospitals, or other entities, as GAO did for their 2012 report. We stated that we did not believe this approach meets the requirement in section 1834(l)(17)(B)(ii) of the Act for a representative sample because many ambulance suppliers and all ambulance providers share operational costs with fire, police, health care delivery or other activities. We also considered including providers' and suppliers' total costs and revenues across all activities and stated that while this would simplify cost and revenue data reporting, the resulting data would not be limited to ground ambulance activities, and therefore, would result in biased estimates of ground ambulance costs or require significant assumptions to estimate ground ambulance costs alone.

To more accurately define total costs and total revenues related to ground ambulance services for those ground ambulance organizations that provide other services in addition to ground ambulance services, we proposed an approach where the data collection instrument instructions would separately address three further refined proposed categories of total ground ambulance costs and revenues:

- Cost and revenue components completely unrelated to ground ambulance services. In the proposed rule, we stated these costs and revenues would be unrelated to this data collection and not reported. We gave examples that included administrative staff without ground

ambulance responsibilities, health care delivery outside of ground ambulance, community paramedicine, community education and outreach, and fire and police public safety response.

- Cost and revenue components partially related to ground ambulance services. We stated these costs and revenue would be reported in full, but respondents would report additional information that could be used to allocate a portion of the costs to ground ambulance services. We stated that depending on how the data would be utilized, certain costs could be included or excluded from an analysis after data are collected. We provided examples to include EMTs who are also firefighters and facilities with both ground ambulance and fire department functions. (We stated that we considered an alternative where respondents would allocate costs and report only costs associated with ground ambulance services but believed that would pose an additional burden on the respondent to calculate allocated amounts, and would result in an allocation process that is less transparent and standardized).

- Cost and revenue components entirely related to ground ambulance services. We stated that these costs are reported in full. We gave an example to include EMTs with only ground ambulance responsibilities and ground ambulance vehicles.

In the proposed rule, we stated that we believe that this approach will enable us to collect the data necessary to evaluate the adequacy of payments for ground ambulance services, the utilization of capital equipment and ambulance capacity, and the geographic variation in the cost of furnishing such services. We stated that the data could be analyzed in the same manner as the data in the GAO report, for example, calculating an average per-transport cost for each organization and calculating Medicare margins with and without add-on payments, or could provide the basis for other analyses to link reported costs to AFS rates. We stated that an analysis could use reported total costs and information on the volume of transports by levels of

services to estimate a cost for each HCPCS code reported for the AFS, or regression-based approaches to estimate the marginal cost of furnishing each HCPCS code on the AFS. We stated that we believed that under our approach, the collected data will be available to estimate total costs and revenue relevant to ground ambulance services.

We received comments on scope of cost, revenue, and utilization data.

Comment: Many commenters stated that they support CMS' approach to collect data on total costs related to ground ambulance services, total revenue from ground ambulance services, and total ground ambulance service utilization. They stated that they support this approach because it will provide the most accurate and complete view of ground ambulance costs, revenue, and utilization.

Commenters also expressed support of CMS' proposal to collect data in such a way that will allow the allocation of a share of organizations' total costs to ground ambulance services in cases where an organization also provides other services or activities. Commenters stated that separating ground ambulance costs from non-ground ambulance costs is essential for the data collection system to comply with the intent of the Congress when it established the new program. They also stated that they agree that the data collection instrument should provide clear instructions to separately address these costs while in many cases allowing them to be reported and that the clear definition of these terms will be critically important to ensure the consistent application of these categories.

Finally, one commenter expressed concern that several categories of "hidden" or "opportunity" costs were not captured in the data collection instrument. These include, but are not limited to: volunteers using their own cars to respond to calls; the time/money volunteers lose in responding to calls, and position vacancies that organizations cannot fill or needed capital

equipment or buildings that they cannot purchase due budget constraints. The commenter noted these “hidden costs” artificially lower the cost of running an ambulance service for some organizations.

Response: We agree that it is critical to collect data in such a way that ground ambulance costs can be separated from an organization’s total costs in cases where an organization performs ground ambulance and other activities. The approach that we proposed would collect information in such a way that analysts (rather than the respondent) would be able to allocate many costs to ground ambulance services.

We also do not agree with the commenter who suggested that we collect information on what they described as “hidden” costs. The statute requires us to collect information on actual costs, not on costs that would have occurred under certain circumstances. We believe that the proposed data collection instrument will provide the necessary data required by the statute, and collecting information on other costs or potential costs would be out of scope for this data collection.

After consideration of the comments, we are finalizing our proposals to collect data on total costs related to ground ambulance services, total revenue from ground ambulance services, and total ground ambulance service utilization. We are also finalizing our proposals regarding allocation of a share of organizations’ total costs and revenues unrelated to, partially related to, and entirely related to ground ambulance services.

c. Final Data Collection Elements

In the proposed rule, we shared the proposed data collection instrument on the CMS website at <https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html>. We provided an overview of the elements of the data collection instrument we proposed in Table 37,

including information on costs, revenues, utilization (which we define for the purposes of the data collection instrument as service volume and service mix), as well as the characteristics of ground ambulance organizations.

In the proposed rule we stated that to help structure the data collection instrument, we organized costs by category (for example, labor, vehicles, and facilities), which we stated was the approach used in the GEMT and the AAA/Moran survey.

TABLE 37: Components for the Data Collection Instrument

Component (Data Collection Instrument Section)	Broad Description
Ground ambulance organization characteristics (2-4)	Information regarding the identity of the organization and respondent(s), service area, ownership, response time, and other characteristics; broad questions about offered services to serve as screening questions.
Utilization: Ground ambulance service volume and service mix (5 and 6)	Number of responses and transports, level of services reported by HCPCS code.
Costs (7-12)	Information on all costs partially or entirely related to ground ambulance services.
• Staffing and Labor Costs (7)	Number and costs associated with EMTs administrative staff, and facilities staff; separate reporting of volunteer staff and associated costs.
• Facilities Costs (8)	Number of facilities; rent and mortgage payments, insurance, maintenance, and utility costs.
• Vehicle Costs (9)	Number of ground ambulances; number of other vehicles used in ground ambulance responses; annual depreciation; total fuel, maintenance, and insurance costs.
• Equipment & Supply Costs (10)	Capital medical and non-medical equipment; medical and non-medical supplies and other equipment.
• Other Costs (11)	All other costs not reported elsewhere.
• Total Cost (12)	Total costs for the ground ambulance organization included as a way to cross-check costs reported in the data collection instrument.
Revenue (13)	Revenue from health insurers (including Medicare); revenue from all other sources including communities served.

(1) Collecting Data on Ground Ambulance Provider and Supplier Characteristics

We are required to collect information regarding the geographic location of ground ambulance organizations to meet the requirement at section 1834(l)(17)(A)(iii) of the Act that the collected data include information on services furnished in different geographic locations,

including rural areas and low population density areas. In the proposed rule, we stated that we recognized that there are differences between and among ground ambulance organizations on several key characteristics, including geographic location; ownership (for-profit or non-profit, government or non-government, etc.); service volume, organization type (including whether costs are shared with fire or police response or health care delivery operations); EMS responsibilities; and staffing models. We stated that our research indicated that:

- There are differences in costs per transport by ground ambulance organizations with a different ownership status;
- EMS level of service and staffing models often have an important impact on costs, with higher EMS levels of service (for example, quicker response times) and static staffing models (that is, maintaining a constant response capability 24 hours a day, 7 days a week, 365 days a year) involving higher fixed costs; and
- Utilization varies significantly across ambulance providers and suppliers of different characteristics.

Due to this variation in characteristics and the effect it has on costs and revenues, we stated that we believed it is important for ground ambulance organizations to report additional characteristics to adequately analyze the differences in costs and revenue among different types of ambulance providers and suppliers. We also stated that we believed collecting this information directly through the data collection instrument will improve data quality with minimal burden on the respondents because the data collection instrument was designed to tailor later sections and questions based on respondents' characteristics through programmed "skip patterns". We stated we considered relying exclusively on the Medicare enrollment form CMS 855A for ground ambulance providers or CMS 855B for ground ambulance suppliers to capture

this information, but believed that data accuracy would be more robust if reported directly by respondents for the specific purpose of this data collection.

We proposed to collect information on ownership and organization type through a sequence of questions in Section 2 of the data collection instrument. We stated that some of the questions in this section were adapted in part from prior surveys (such as the GAO and Moran surveys) with changes as necessary to fit scenarios reported during interviews with ground ambulance organizations. The first question related to organizational characteristics, question 6, asked about the organizations' ownership status and aligned closely with a similar question on the Medicare enrollment form CMS 855B for ambulance suppliers. Question 7 asked whether the respondent's organization used any volunteer labor. While this question could have been asked later in the data collection instrument around the collection of labor data, we stated we opted to include it here because many ground ambulance organizations informed CMS that they view the use of volunteer labor as a defining organizational characteristic, on par with ownership status, and that a volunteer labor question was expected by respondents at this early point in the data collection instrument. Question 8 asked respondents to select a category that best describes their ambulance organization. We stated that the response options for this item are mutually exclusive and align with the ambulance provider and supplier taxonomy described in the CAMH report. The next two questions, 9 and 10, more directly asked whether the respondent has shared operational costs with an entity of another type, including a fire department, hospital, or other entity. We stated that we proposed these questions in addition to the organization type question to account for situations where a respondent might primarily identify as an organization of one type (with implications for shared operational costs) but then might have shared operational costs with another entity type. We stated that responses to questions 9 and 10 play an important role

in skip logic later in the data collection instrument regarding questions and response options relevant only to ground ambulance organizations with shared operational costs with an entity of another type.

We stated that other questions regarding organizational characteristics are necessary to tailor later parts of the data collection instrument to the respondent. These included questions in Section 2 of the data collection instrument on whether the respondent's ambulance organization:

- Is part of a broader corporation or other entity billing under multiple National Provider Identifiers (NPIs) (question 2).
- Routinely responds to emergency calls for service (question 11).
- Operates land, water, and air ambulances (questions 12-14).
- Has a staffing model that is static (that is, consistent staffing over the course of a day/week) or dynamic (that is, staffing varies over the course of a day/week) or combined deployment (certain times of the day have a fixed number of units, and other times are dynamic depending on need) (question 15).
- Provides continuous (also known as “24/7/365”) emergency services) (question 16).
- Provides paramedic or other emergency response staff to meet ambulances from other organizations in the course of a response (questions 17 and 18).

In our interviews with ambulance providers and suppliers, some participants indicated that their staffing model is an organizational characteristic that would likely be associated with costs per transport and that organizations that need to maintain fixed staffing levels over time (for example, to maintain an emergency response capability to serve a community) would likely have higher costs than those that do not.

Section 1834(l)(17)(A)(iii) of the Act requires collecting data from ambulance providers and suppliers in different geographic locations, including rural areas and low population density areas. In the proposed rule, we stated that the area served by ambulance organizations is an important characteristic and we proposed to collect information on the geographic area served by each ambulance organization in Section 3 of the data collection instrument.

In the proposed rule, we stated that many ground ambulance organizations have a primary service area in which they are responsible for a certain type of service (for example, ALS-1 emergency response within the borders of a county, town, or other municipality) and may have secondary services areas for a variety reasons, such as providing mutual or auto aid, or providing a different service in a secondary area (for example, non-emergency transports state-wide). For the proposed rule, we considered several alternatives to collect information on service area. One option was to utilize Medicare claims data, but we stated that this would limit the information to Medicare billed transports only and would also not differentiate between primary and other service areas. Another option was to allow respondents to write in a description of their primary and other service areas, but we stated this would require converting written responses to a format that can be used for analysis. A third option was for respondents to report the ZIP codes that constitute their primary and other service area. We stated this approach aligns with the Medicare enrollment process requirement to submit ZIP codes where the ground ambulance organization operates and that it would also collect ZIP code-based information on service area that can be easily linked to the ZIP Code to Carrier Locality file⁹⁶ that lists each ZIP code and its designation as urban; rural; or super-rural. We stated that this file is used by the MACs to determine if the temporary add-on payments should apply to a transport under the AFS.

⁹⁶ Available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/index.html>.

We also stated the main limitation of this approach is that ZIP codes would not always align to service areas, because ZIP codes routinely cross town, county, and other boundaries that are likely relevant for defining ground ambulance organizations' service areas.

We proposed to require ground ambulance organizations that are selected during sampling to identify their primary service area by either: (1) providing a list of ZIP codes that constitute their primary service area; or (2) selecting a primary service area using pre-populated drop-down menus at the county and municipality level in question 1, Section 3 of the data collection instrument. We also proposed to require respondents to specify whether they have a "secondary" service area, which we stated are areas where services are regularly provided under mutual aid, auto-aid, or other agreements in Section 3, question 4 of the data collection instrument and if so, to identify the secondary service area using ZIP codes or other regions as described above for the primary service area (Section 3, question 5). We stated that mutual aid agreements are joint agreements with neighboring areas in which they can ask each other for assistance and that auto-aid arrangements allow a central dispatch to send the closest ambulance to the scene. We did not propose to collect information on areas served only in exceptional circumstances, such as areas rarely served under mutual or auto-aid agreements or deployments in response to natural disasters or mass casualty events because we stated we believe reporting on rarely-served areas will involve significant additional burden and will add to complexity of the data collection instrument without generating data that will be useful for analysis.

In the proposed rule, we stated that the proposed approach distinguishes between primary and secondary service areas and will allow subsequent questions on the balance of transports in a respondent's primary versus secondary service area and whether average trip time and response times are substantively longer in the secondary versus primary service area. We stated that we

believed this approach results in data that can be easily analyzed and eliminates the need to ask certain other questions (such as the population and square mileage of the respondent's service area) because this information can be inferred using the reported geographic service area boundaries.

We proposed to ask the following questions in Sections 3 and 4 of the data collection instrument, service area and subsequent emergency response time, because the responses to these questions are closely related to the area served by the organization:

- Whether the respondent is the primary emergency ambulance organization for at least one type of service in their primary service area (Section 3, question 2).
- Average trip time in primary and secondary service areas (Section 3, questions 3 and 6).
- Average response time (for organizations responding to emergency calls for service) for primary and secondary service areas (Section 4, questions 1- 2).
- Whether the organization is required or incentivized to meet response time targets by contract or other arrangement (for organizations responding to emergency calls for service) (Section 4, question 3).

In the proposed rule, we stated that average trip and response time are necessary to understand how geographic distance between the ground ambulance organization's facilities and patients affects costs. In interviews, ground ambulance organizations recommended the collection of average trip time in addition to mileage because some rural and remote areas may have relatively long average trip times even though mileage may be more modest due to terrain, the quality of roads, and other factors. We stated that we believed that collecting information on

average response time would allow the analysis of whether communities with different response time expectations and targets have systematically different costs.

We received comments on collecting data on ground ambulance provider and supplier characteristics. The following is a summary of the comments we received and our responses.

Comments: Many commenters stated that they are pleased that CMS has recognized the importance of taking into account organizational characteristics in designing the data collection instrument. They stated that even though the organizational characteristics in Section 2 of the data collection instrument differ from those initially recommended by the AAA based on its work with the Moran Company, they believe that in its totality the data collection instrument covers the key organizational characteristics that policy-makers will need to use to accurately determine the cost of providing ground ambulance services. Commenters made several specific recommendations. One commenter recommended that CMS add questions asking whether the respondent has sole source contracts or local jurisdictional requirements and suggested that we add categorical response options (specifically, less than and greater than 20 percent) to the existing question on the use volunteer labor because these characteristics may be systematically related to reported costs and revenue.

Commenters also asked CMS to consider several specific clarifying changes to the data collection instrument including: (1) clarifying how respondents should respond to question 1 in Section 2 if they have multiple service types under the same NPI; (2) defining NPI; (3) distinguishing between response options for independent/proprietary organization types; (4) specifying which organization name should be reported; (5) defining the term “public/private partnership;” (6) adding an “other” organization type; (7) clarifying the term ‘volunteer’ and which volunteer personnel are in-scope when reporting volunteer labor; and (8) clarifying how to

classify 501(c)(4) organizations.

Many commenters requested that because the questions in Section 4, emergency response time, are similar to those in Section 3 of the data collection instrument, they would like CMS to provide the same clarification to these questions that they highlighted for Section 3 of the data collection instrument.

One commenter requested clarification on whether the average trip time is calculated across all calls or just specific types such as emergency, scheduled, etc. One commenter recommended that average response time be defined as starting when the call for service is answered to when the first EMS unit arrives on location. The commenter stated this definition is best because it measures response times as experienced by the public/patient. One commenter requested clarification on Section 4, Question 3 which asks whether organizations are penalized for exceeding response time targets, if their local area imposes these standards. The commenter requested clarification on whether any performance penalties should be included in the answer to this question or only response time penalties.

Several commenters also recommended asking ground ambulance organizations to provide 90th percentile response time rather than average response time. They believe 90th percentile response time is a more accurate indicator of ambulance services capabilities and quality. They stated that average time has too wide a range for error, since roughly half of responses are quicker/slower than average. They further stated that using average response time also tends to flatten the data, which means that the fastest and slowest organizations do not stand out as much.

Response: We appreciate commenters' points that much of the information collected via the data collection instrument will be useful in describing variation across ground ambulance

organizations. Many of the specific characteristics that commenters suggested adding to the initial section of the data collection instrument are already included in the survey. For example, Section 3 of the proposed data collection instrument asks if the organization is the only EMS provider in most or all of their service area, Section 4 asks about response time targets, and Section 7 asks for detailed information related to volunteer labor. We added screening questions to the initial section of the data collection instrument only when they were necessary to inform skip patterns, and reserved asking other questions until later sections. The information collected via the survey can be used to conduct analyses for various subgroups of organizations, for example those that are and are not the only EMS provider in part or all of their service area.

We thank commenters for pointing out several opportunities to clarify the instructions and items in the proposed data collection instrument. We believe that based on the wording of question 1, Section 2, organizations with more than one service line under the same NPI (such as both air and ground ambulance) should answer “yes” to question 1 in Section 2. We agree that the term national provider identifier should be defined at its first use in the data collection instrument. When distinguishing between different types of proprietary/independent ground ambulance organizations, we intended option (e) to reflect primarily EMS responsibilities and option (f) to reflect primary responsibilities that are non-emergency. For the legal name, we are requesting that organizations use their legal name, which should match the name used on their Medicare enrollment form 855B in most cases. For this reason, we encourage all ambulance organizations to confirm that their information is up-to-date in the Medicare enrollment database, the Provider Enrollment Chain and Ownership System (PECOS). A public/private partnership is a formal contractual arrangement between a government and an entity chartered for the express purpose of providing the service. We believe that the response options for the ownership type

item (question 6 in Section 2) are comprehensive and no additional “other” option is necessary. The volunteer labor question refers to any volunteers, including non-medical personnel. Any staff member who is paid could not be counted twice, once as a paid staff member and once as a non-paid staff member or volunteer. So in the example of a paid administrator who serves as a volunteer responder, they should be counted in the administrator category since that is the category in which they are paid. Volunteers may receive some forms of compensation but are not considered full or part time employees if they are not paid a minimum wage in return for full or part-time labor. Finally, 501(c)(4) organizations are considered to be for-profit organizations.

We agree that most ground ambulance organizations that respond to emergency calls for service already track response times and that different organizations may use different methodologies for tracking. We also agree that it is important to define the term “average response time” to ensure respondents are reporting times measured in a consistent way but we are concerned that specifying one definition or another may result in additional burden for organizations that currently track response time using another definition. We believe that several summary statistics would be useful for analysis, including an estimate of central tendency (like the mean) and an estimate focusing more on outliers (like the 90th percentile). We are also clarifying that response time target penalties do not include performance or any other type of penalties.

As a result of these comments, we will change two of the options in Question 8 to (e) Independent/proprietary organization primarily providing EMS services and (f) Independent/proprietary organization providing non-emergency services. We will also add information on the use of volunteers to clarify that it refers to all volunteer staff, not only response personnel. We will add the text “that best fits your organization” to Section 2, question

6, and we will define NPI on the first use of that acronym. We will also add new items on whether or not the organization uses the response time definition in the data collection instrument or another definition, new instructions to clarify that respondents should report response times as they currently measure them, and a new item for the 90th percentile response time. We will revise the data collection instrument to add an initial yes/no question asking whether the organization measures response time specifically as the time from when the call for service is answered to when the first EMS unit arrives on the scene. If the respondent answers yes, we would then ask for response time summary statistics. If the respondent answers no, we would ask them to specify what definition they use.

Comment: Many commenters were pleased that the proposed data collection instrument includes questions on their service area because of the impact of the service area on their costs. They described that in some rural areas, ambulance organizations may have to commit vehicles for several hours for a single response if their service areas cover hundreds of miles. In urban areas, an ambulance organization may face a similar challenge of having a vehicle committed to a single response as it navigates traffic congestion and overcrowded emergency rooms. Commenters were also appreciative that we proposed using ZIP code level data, because as the census data changes, so do the ZIP codes designated as urban, rural, and super-rural. They stated that this information is essential to understand the costs of ambulance organizations providing services in these areas, especially to assess the add-ons and adequacy of current ambulance fee schedule rates. These commenters stated that they appreciate the data elements related to average trip time since having standardized assessment of these elements is also important. They stated that while they had divided the average duration of a transport into three categories, they support the more detailed division in the proposed data collection instrument.

One commenter sought clarification on what CMS means by “primary service area” and “secondary service area”. They inferred that the intent of these distinctions is to allow the end users of the data to be able to allocate the costs appropriately as related to urban, rural, or super-rural areas by proportioning the costs of respondents based on where they provide the most services. They stated that they believe that this approach makes sense as a way to parse out the complexities that an ambulance organization might provide services in more than one geographic designated (for example, urban, rural, super-rural) and that using the ZIP codes rather than the current Medicare definitions of urban, rural, and super-rural will provide consistency in reporting, as the 2020 Census may shift the CMS definitions again. The commenter suggested that, if this assumption is in fact correct, that CMS define the term “primary service area” as the area where more than half of its services are provided. The same commenter asked that CMS provide a standard definition to what it means by “the primary emergency service.” They stated that while many ambulance organizations will likely know whether they are the only provider of emergency services in an area or not, they may not know the volume of services provided by other organizations if there are others providing these services. They also stated that it could also be helpful to know whether CMS will audit the answers to this question and what will be done with the respondents’ data if more than one ambulance organization answers that it is the primary emergency ambulance provider for the same set of ZIP codes. Another commenter requested clarification on whether the secondary service area could include the whole state, or when an organization handles a transfer of a patient to higher level care for another organization.

Response: We thank the commenters for these detailed questions and appreciate the opportunity to provide additional clarification. Each ambulance organization will determine what it considers to be its primary service area, usually based on whether it has primary EMS or

responsibilities within a specific jurisdiction or if it has contractual or other arrangements to provide a certain level of service with a particular region (as opposed to an area where it renders aid to other ambulance organizations). We expect that in most cases, well over 50 percent of an organization's transports will occur in the primary service area. Given the lack of information about ambulance organization service areas, we believe it will be useful to collect respondents' subjective assessment of their own primary and secondary service areas, and do not believe that a specific threshold would be relevant for all respondents. For example, there are likely cases where an organization's primary service area by contract accounts for half or less than half of its paid transports if it serves an area with high levels of mutual or auto-aid agreements. While there are other approaches to collect more detailed information on service areas and the arrangements (both formal and informal), responsibilities, levels of service offered, and service volume in different parts of an organization's service area, we believe that the burden involved in collecting this more detailed information would be considerable. Commenters highlighted several examples of cases where it might be difficult to identify whether they have a secondary service area. If an organization operates an emergency service for one jurisdiction but then operates a non-emergency service in the rest of the state, both may be considered primary since the ground ambulance organization has the primary responsibility for serving both areas. Also, we would not expect that all ground ambulance organizations will have a secondary service area.

We also do not agree with the suggestion to describe primary service areas as those with only one emergency ambulance provider because that would exclude organizations that are the primary emergency ambulance provider in areas where other organizations respond to calls through mutual or auto-aid arrangements on an occasional, but perhaps not an exceptional basis. We understand that ambulance organizations vary in how they define their service areas, and we

expect that ground ambulance organizations will report their service area information accurately. We believe the existing question provides us with the detail we need to understand the service area of the responding ground ambulance organization.

After consideration of the comments, we clarified that responses to questions related to the primary and secondary service area should be based on the respondents' best judgment regarding the definition of their organization's primary service area and, if applicable, secondary service area. We further clarified the primary and secondary service area definitions through the new examples in the data collection instrument instructions and making additional edits pertaining to the service area.

Comment: Several commenters suggested adding a question to Section 3 of the data collection instrument that would ask if the ground ambulance organizations uses EMS employees from another agency, such as a fire department or law enforcement agency, either to provide initial patient care/assessment or continue providing patient care during transportation to a hospital or other destination. If the respondent answers no, they would skip to Section 4. If the respondent answered yes, they would be asked the percentage of patient transports that are EMS employees from another response agencies providing initial patient care/assessment or continuing to provide patient care during transportation, and if the ground ambulance organization reimburses this non-transporting agency for the patient care/assessment services they provide.

Commenters stated that they believe it would be beneficial for CMS to gain an understanding of how frequently ground ambulance agencies rely upon a fire department or law enforcement agency for additional EMS personnel to provide patient care. They stated that while they understand that we are focused mostly on obtaining data related to individual patient

transportation, they believe it is important to consider the entire EMS response system because that is key to evaluating the efficiency and effectiveness of ambulance organizations that rely upon a third-party agencies (such as a fire department or law enforcement agency) to meet their response-time goals.

These same commenters also asked that CMS include a question in Section 4 of the data collection instrument that asks if a ground ambulance organization responds to calls for service in conjunction with a non-transporting EMS agency, such as a fire department or law enforcement agency. If the respondent answers no, they would skip to Section 5 of the data collection instrument. If the respondent answers yes, they would then be asked for additional information including: the percentage of responses in which a non-transporting agency responds initially to the patient; the percentage of transports where an initial responding EMS provider from another agency continue providing patient care during transport to a destination; if they have a formal agreement with the non- transporting agency to provide these services; and if they reimburse the non-transporting agency for these services. Commenters also stated that often ground ambulance organizations may rely upon a non-transporting fire department or law enforcement agency for the initial response to a call for service in order to “stop the clock” and that they believe CMS should include this set of questions to determine how often transporting agencies rely upon a non-transporting agency for initial response and whether the transporting agency is reimbursing the non-transporting fire department or law enforcement agency for this critical response role. Other commenters also suggested that the survey needs to better capture these situations where non-transporting agencies also respond.

Response: The commenters raise an important issue that medical care provided to beneficiaries in emergency settings by the EMS system as a whole consist of more than simply

transporting beneficiaries. Costs may differ for organizations in these situations in important ways; therefore, we agree with the commenters to add one question to the survey that incorporates whether the agency responds to calls with another agency.

After consideration of the comments we added a question in Section 2 of the data collection instrument asking whether the organization responds to calls for service in conjunction with a non-transporting EMS agency, such as a fire department or law enforcement agency. We also added a follow-up question for respondents answering “yes” to collection information on (a) the share of ground ambulance responses during which a non-transporting EMS agency provides staff contributing to the response, and (b) the broad roles of these staff (including EMT-Paramedic, other EMT, and other).

(2) Collecting Data on Ground Ambulance Utilization

CMS is required to collect information on the utilization of ground ambulance services. In the proposed rule we stated that while we could collect information on the volume of ground ambulance services that can be billed to Medicare, this approach would not provide information needed to determine total utilization of ground ambulance organizations. We stated another option would be to utilize Medicare claims data for estimates of ground ambulance transport volume and separately collect information on services not payable by Medicare (such as responses that did not result in a transport), but that this approach would also not provide complete information on total transport volume, since other services, such as responses that do not result in a transport, would not be included.

Based on information provided during interviews with ground ambulance organizations, we identified several distinct utilization categories, such as total responses and ground ambulance responses. In the proposed rule, we stated that this is particularly important for fire-

based and police-based organizations that may have a significant volume of fire and police responses that do not involve a ground ambulance. We stated that the number of responses that did not result in a transport can be separately tallied. We also stated that other important utilization categories are ground ambulance transports (that is, responses during which a patient is loaded in a ground ambulance), which can be measured in terms of total transports (that is, all ground ambulance transports regardless of payor) or paid transports (that is, transports for which the ambulance provider or supplier was paid in part or in full). Additionally, we stated that another utilization category would include information on ambulance providers and suppliers that furnish paramedic intercept services or provide paramedic-level staff in the course of a BLS response where another organization provides the ground ambulance transport.

In the proposed rule, we stated we believed it is important to collect utilization data related to all services, not just transports, because other services that contribute to the total volume of responses have direct implications for costs and that collecting utilization information related to transports without collecting information on other services would omit important cost information. We stated that some utilization measures, such as the ratio of ground ambulance to total responses, may be one basis for allocating certain costs reported elsewhere in the data collection instrument. We stated that another example would be the difference between total and paid transport, as this would provide information on services that were provided to patients but for which no payment is received.

To best capture the full range of utilization data, we proposed a two-pronged approach to collect data on the volume and the mix of services. First, we proposed to collect total volume of services for each of the categories listed below in Section 5 of the data collection instrument:

- Total responses, including those where a ground ambulance was not deployed (question 1).
- Ground ambulance responses, that is, responses where a ground ambulance was deployed (question 2).
- Ground ambulance responses that did not result in a transport (question 4).
- Ground ambulance transports (question 5).
- Paid ground ambulance transports, that is, ground ambulance transports where the ambulance provider or supplier was paid for a billed amount in part or in full (question 6).
- Standby events (question 7).
- Paramedic intercept services as defined by Medicare (question 8).
- Other situations where paramedic staff contributes to a response where another organization provides the ground ambulance transport (question 9).

The CAMH report describes several cases where an ambulance provider or suppliers' mix of services within one of the utilization categories described above could affect costs or revenue. Most importantly, within billed transports, variation in the mix of specific ground ambulance services (for example, ALS versus BLS services) will affect both costs (because ALS transports require more and more costly inputs) and revenue (because ALS services are generally paid at a higher rate). We stated that ground ambulance organizations with a higher share of responses that are emergency responses may also face higher fixed costs, and that the costs for organizations furnishing larger shares of water ambulance transports are likely different than costs from organizations that do not furnish water ambulance transports. We stated that there is a subset of ground ambulance organizations that specialize in non-emergency transports or inter-

facility transports, which suggests that this business model may result in different per-transport costs compared to EMS-focused ambulance providers and suppliers.

Second, to account for this significant variation, we proposed to collect the following information related to service mix:

- The share of responses that were emergency versus non-emergency (Section 6, question 1).
- The share of transports that were land versus water (asked only of organizations reporting that they operate water ambulances; Section 6 question 2).
- The share of transports by service level (Section 6 question 3).
- The share of transports that were inter-facility transports (Section 6 question 4).

We did not propose that respondents report on their mix of services in primary and secondary service areas (as defined above) separately because this would double the length of this section of the data collection instrument and require complex calculations or use of assumptions by respondents that do not separately track services by area. Instead, we proposed that respondents report the share of total ground ambulance responses that were in a secondary rather than primary service area in a single item (Section 5 question 3). We also did not propose to collect detailed information regarding the mix of services for total transports (versus paid transports) and paid transports (versus total transports) because collecting information on the mix of services for total and paid transports separately would double the reporting burden in this section and because we believed, based on discussions with stakeholders, that it is reasonable to assume that the distribution of transports across categories would be the same.

We received comments on collecting data on ground ambulance utilization and service mix. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that they were pleased that CMS proposed to collect utilization data on all services, not just transports, in Section 3 of the data collection instrument. These commenters stated that they agree with CMS that these data are important because other services that contribute to the total volume of responses have direct implications for costs. They also stated that given the importance of this information to determining and evaluating the costs of providing ground ambulance services, they asked that CMS add “low,” “medium,” and “high” response options to allow the data to be separated by the volume of services provided by each respondent. They stated that while that information might be obtained by adding the various questions in Section 5 of the data collection instrument, adding such a question would allow for evaluators to have a more straight-forward and consistent method of taking this critical factor into account. They stated that by setting the definition of low, medium, and high volume, CMS would be standardizing the way in which these terms are used by anyone seeking to use the data to develop policy and that standardization is critically important when policies such as low-volume adjusters are being considered.

Several commenters requested clarifications on the definitions of “ground ambulance,” “response,” and “transport, including removing the Medicare definition of ‘medically necessary’ from the definition of transports because it is not uniform across payers. For items related to service mix, one commenter suggested using the Medicare manual definitions of specific ground ambulance services to avoid confusion. Commenters also suggested clarifications to the definition of “interfacility transport.”

Another commenter suggested several points of clarification on responses and transports. The commenter stated that it was not clear how to count responses for situations when multiple ambulances may be dispatched to the scene, but not all of them transport beneficiaries. They

suggested that responses should actually be the number of ambulances sent to the scene. This same commenter also requested clarification on whether responses where a police car is first on the scene and then cancels the ambulance should be counted in responses, and whether community paramedicine visits should be counted.

One commenter requested clarification about how to treat transfers that are ‘emergency.’ The commenter noted that in rural areas, transfers can be considered emergency calls when a patient needs to be transported to a higher level of care. They requested clarification on how an emergency transfer should be counted in the responses and transports. This commenter also requested clarification on how ground ambulance organizations who receive some local tax funding to offset the patients who do not pay should report unpaid transports since in this scenario all patients’ transports are partially paid.

Many commenters noted that, while they believe it is important to collect information on responses that do not result in transports, they believed some ground ambulance organizations do not currently track this information. These commenters suggested that CMS add new response options to allow respondents to either estimate the share of responses where the patient is not transported or to report that this information is not available.

Several commenters noted that they incur significant costs for ground ambulance where the patient is pronounced dead at the scene. These commenters asked that CMS add several items to the data collection instrument to collect information on the share of responses that involve a patient pronounced dead on-scene and the time and costs involved in these responses.

Response: We appreciate the detailed comments to our proposals, but do not agree that respondents should be presented with an option to report service volume in terms of categorical “low,” “medium,” and “high” response options. Data collected using this categorical approach

would considerably decrease the precision of estimated per-transport costs. We also believe that it would be challenging to combine data from ground ambulance organizations reporting specific counts of services with those opting to use the categorical response options. Reported counts of services can easily be described in terms of categories when the data is analyzed.

We agree that it is appropriate to use Medicare manual definitions for ground ambulance services, although some of the verbatim descriptions may need to be abridged due to their length. We appreciate commenters' concerns that the specific Medicare definition of ground ambulance transport may not apply to transports paid by certain other payers. While we would generally prefer to use the Medicare definition of ground ambulance transports, we believe that the burden of asking respondents to distinguish between transports paid by other payers that would or would not have met Medicare requirements would be unreasonable compared to incremental benefit of using this narrower definition. We agree that the definition of interfacility transport in the data collection instrument needs to be clarified and revised. We agree that the commenters' specific clarifications to the definitions of several service categories will be helpful to respondents.

In the data collection instrument, the term 'ground ambulance response' is defined as "a response by a fully equipped and staffed ground ambulance, scheduled or unscheduled, with or without a transport, and with or without payment. If more than one vehicle is sent to the scene, the instructions are to count this as one response." For example, if three ambulances are sent to one incident, and only one ambulance transports a patient, then this example is counted as one response and one transport. Similarly, responses where another EMS vehicle arrives and cancels the ambulance would not be counted in the responses. While there may be some discrepancy between the number of responses, paid transports and responses that do not result in a transport, we do not agree with the suggestion to allow for multiple ambulances sent to one scene to be

counted as multiple responses since we do not encourage ground ambulance organizations to send more than one ambulance on every call.

Emergency transfers would be counted in the number of emergency responses in Section 6, Question 1, and under their corresponding level of service in Question 3. Paid transports should only include those where a health insurer or patient paid for some or all of the billed charge. Any payments that are offset by tax revenue should not be counted in this section since tax revenue is reported separately in the revenue section.

We agree with commenters that it is important to collect information on the number of responses that do not result in a transport, and understand that some ground ambulance organizations may not currently track this information. Due to the importance of this information for determining cost, we do not believe that adding the response options to report that the information is not available or to allow respondents to estimate the share of responses where the patient is not transported is appropriate.

The proposed data collection instrument asks respondents to report the share of responses that do not result in a transport for any reason, including that the death of the patient. We are collecting information on all ground ambulance costs, regardless of whether the patient was transported. Given our overarching goal of minimizing burden while collecting the data necessary, we believe that existing items collecting information on the number of responses that did not result in a transport are sufficient.

After consideration of the comments, we used the Medicare manual definitions of Medicare ground ambulance services, clarified the definitions of other response and transport categories, and removed the Medicare medical necessity requirement from the definition of “ground ambulance transport.” We also refined the definition of “interfacility transport” in the

data collection instrument to include transports where “the origin and destination are one of the following: a hospital or skilled nursing facility that participates in the Medicare program or a hospital-based facility that meets Medicare’s requirements for provider-based status. We also added an additional question to the data collection instrument that specifically asks for interfacility transports that are covered under Medicare Part A where the ambulance provider or supplier would seek payment from SNF, hospital, or hospice.

Finally, we clarified the instructions for the definitions of response and transports, incorporating the example of an emergency transfer.

(3) Collecting Data on Costs

Section 1834(l)(17)(A) of the Act requires CMS to collect cost information from ground ambulance organizations. This section describes the data in each cost category that we proposed to collect, as well as alternatives that we considered.

In the proposed rule we stated that the costs reported separately in the categories of costs we proposed to collect would sum to an organization’s total ground ambulance costs. In addition to ground ambulance costs, we proposed to ask all respondents in the data collection instrument to report their total annual costs (that is, operating and capital expenses), inclusive of costs unrelated to ground ambulance services, in a single survey item (Section 12, question 1). For ground ambulance organizations that do not have costs from other activities (such as from operating a fire or police department), the reported total costs are a way to cross-check costs reported in individual cost categories throughout the data collection instrument, and we can compare the reported total to the sum of costs across categories. In the proposed rule, we stated that such a cross-check may also be appropriate for ground ambulance organizations with costs from other activities, as the sum of costs across ground ambulance cost categories should always

be less than the ground ambulance organization's reported total costs. We stated that we believed that this cross-check will improve data quality and is consistent with existing survey-based data collection tools and that this approach would provide a better understanding of the overall size and scope of ground ambulance organizations, including activities other than providing ground ambulance services and that relatively larger organizations may have lower ground ambulance costs due to economies of scale and scope.

To avoid reporting the same costs multiple times, we included instructions and reminders throughout the data collection instrument to avoid double-counting of costs. We stated that from a design perspective, we believe it is less important where a particular cost is reported on the data collection instrument and more important that the cost is reported only once.

We made two proposals that have important implications for reporting in all cost sections in the data collection instrument. First, in the case where a sampled organization is part of a broader organization (such as when a single parent company operates different ground ambulance suppliers), we proposed to ask the respondents to report an allocated portion of the relevant ground ambulance labor, facilities, vehicle, supply/equipment, and other costs from the broader parent organization level in separate questions in several places in the cost sections of the data collection instrument (Section 7.2 question 3, Section 8.2 question 2, Section 8.3 question 2, Section 9.2 question 5, Section 9.3 question 6, Section 10.2 question 4, and Section 11 questions 2 and 5). This scenario is discussed in more detail in the sampling section below. In exploratory analyses, we found that a small share of NPIs were part of broader parent organizations. Due to the rarity of this scenario and the complexity of calculations required, we proposed to allow the respondent to report an allocated amount directly for these questions using an allocation approach they regularly use for this purpose. We stated that while a specific

allocation approach would yield more uniform and transparent data, we believed that these benefits were not worth the additional respondent burden.

Second, we proposed to include a general instruction stating that in cases where costs are paid by another entity with which the respondent has an ongoing business relationship, the respondent must collect and report these costs to ensure that the data reported reflects all costs relevant to ground ambulance services. We provided examples including when a municipality pays rent, utilities, or benefits directly for a government or non-profit ambulance organization, or when hospitals provide supplies and/or medications to ground ambulance operations at no cost. During interviews with ground ambulance organizations, we were told that there are many nuanced arrangements that fit this broad scenario. In the proposed rule, we stated that although we recognized this would be an additional step for some ground ambulance organizations, we are concerned that the lack of reported cost data in one of these major categories could significantly affect calculated total cost.

Because some ambulances, other vehicles, and buildings are donated to ground ambulance organizations, we stated that we considered asking respondents to report fair market values for these vehicles and buildings. We stated our concern that the lack of reported cost data in one of these major categories could affect calculated total cost, as well as our understanding that it is not always clear what cost is appropriate to report. To avoid the subjectivity and burden involved in asking respondents to report fair market value, we proposed that respondents report which ambulances, other vehicles, and buildings have been donated, but not an estimate of the fair market value of those donations. We stated we believe fair market values could be imputed using publicly available sources of data to facilitate comparison of data between organizations that have donations and those that do not. For the same reasons, we also proposed not to collect

an estimate of fair market value for donated equipment, supplies, and costs collected in the “other costs” section of the data collection instrument. We stated that for those ground ambulance organizations with costs that were paid by another entity with which the respondent has an ongoing business relationship, such as a ground ambulance organization that is part of or owned by a government entity, respondents would obtain the cost information directly from that entity since we would not consider these to be donated items.

We received general comments on collecting data on ground ambulance costs. The following is a summary of the comments we received and our responses.

Comment: Commenters were supportive of the categories of costs that we proposed for the data collection system. Commenters stated that they support collecting total ground ambulance costs across all cost data elements, without limiting the costs to those associated with transports and as a result, the cost of readiness will be embedded in the response for each cost category and then be automatically allocated across the services provided. However, one commenter suggested including an explicit question to measure readiness costs: total trip time multiplied by total responses divided by total scheduled ambulance unit hours (total ambulance labor hours reported for a week divided by 2 as typically there are 2 personnel on an ambulance).

Commenters were also supportive of the proposal to have respondents report total annual costs that include the operating and capital expenses inclusive of costs unrelated to ground ambulance services in a single survey question, as well as CMS’ efforts to eliminate double-counting of costs. Several commenters requested clarification that the total cost and total revenues section include non-ground ambulance related costs/revenues.

Commenters stated that they in general support the allocation rules as proposed. Several commenters recommended collecting costs paid by another entity in the data collection

instrument and for inclusion in any analysis of Medicare margins so that the costs will not be artificially low and provided the example of including the labor provided by non-transporting organizations at the scene. Another commenter was concerned it may be difficult to obtain costs paid for by other entities for which they have an ongoing business relationship such as a municipality paying for dispatch services.

Commenters supported CMS' proposal to ask reporting ground ambulance organizations that are part of broader parent organizations (for example a broader for-profit corporation billing Medicare for ground ambulance services under multiple NPIs) to submit information related to an allocated share of their parent organization's costs. One commenter specifically recommended that CMS use the term "central office" rather than "parent organization" in the data collection instrument and suggested that CMS specify a specific allocation methodology that respondents must follow in this scenario to avoid concerns of differences in how these costs are reported across organizations. Another commenter asked that CMS take the reported estimates of allocated parent organization costs in good faith, without the threat of audits as the data may be difficult for organizations to report, particularly in the initial years of data collection.

One commenter requested that respondents be asked to estimate the fair market value of any ambulances, other vehicles, and buildings that have been donated, rather than relying on CMS or MedPAC to impute these values. The commenter stated they believe respondents could be given the option of identifying the estimated value as of the year the item was donated (and the year it was donated), if that is less burdensome than estimating the current value. They thought that respondents would be in a much better position to accurately estimate these values than CMS or MedPAC.

One commenter stated that many small ground ambulance organizations do not keep track of data on depreciation and was concerned that any of the sections asking for depreciation would be difficult to fill out for some ground ambulance organizations.

Response: The survey is designed to collect information on total costs, which implicitly captures all costs related to readiness, and therefore, we do not believe it necessary to include a separate question that requires ground ambulance organizations to calculate a readiness cost.

We believe that while some commenters noted the lack of a standard approach to the allocation of costs between ambulance organizations and their parent organization or central office could potentially lead to differences in how these costs are reported, we do not believe that developing a specific, standardized allocation method for these costs is necessary, as we expect only a small share of reporting ground ambulance organizations to allocate parent organization costs in this way.

The questions for total costs and total revenue currently specify that services not related to ground ambulance services should be included, but we agree with the commenter suggesting the addition of a question on fees paid to other non-transporting organizations for their services, when there is an agreement in place to pay for these services. However, as we discuss elsewhere in these comments, we continue to believe that requiring ground ambulance organizations to report on the estimated costs of labor, supplies, vehicles, etc. for non-transport vehicles that are ‘in-kind’ donations would be extremely burdensome for ground ambulance organizations that do not currently pay for these services. However, if a cost that is borne directly by the ground ambulance organization or another entity that owns, operates, or manages the ground ambulance organization, then that cost is required to be reported.

We acknowledge that certain items such as depreciation will be difficult for some

agencies to estimate and we will provide additional instructions on how to estimate depreciation in the survey instructions. However, we disagree with the commenter regarding collecting fair market value from respondents because we want to reduce any subjectivity and burden involved in asking respondents to report fair market value. We continue to believe fair market values could be imputed using publicly available sources of data to facilitate comparison of data between organizations that have donations and those that do not. We believe the data collected on the survey will allow end users to infer approximate costs for donated items.

After consideration of the comments, we added a question to the ‘other costs’ section for funds paid to other organizations for services (such as non-transporting organizations providing medical personnel).

(i.) Collecting Data on Staffing and Labor Costs

As we discussed in the proposed rule, ambulance organizations told us in interviews that labor is one the largest contributors to total ground ambulance costs (especially medical staff such as EMTs, paramedics, and medical directors). They told us that they use a broad mix of labor types and hiring arrangements, and that there is significant variation in tracking staffing and labor cost inputs that are needed to calculate costs. We were also informed by ambulance organizations that data on the number of ground ambulance staff and associated labor costs were often available at one of three levels: the individual employee level; aggregated by category such as EMT-Basic or Medical Director; or aggregated across all staff. Additionally, we were told by ambulance providers and suppliers that ground ambulance organizations typically face challenges in tracking ground ambulance staff and costs by category when staff had multiple ground ambulance responsibilities (for example, EMTs with supervisory responsibilities, EMTs who are also firefighters, etc.).

In the proposed rule we stated that we agree that labor costs are an important component of total costs and believed that it is necessary to collect information on both staffing levels, that is, the quantity of labor used, and the labor costs resulting from these labor inputs. Without information on staffing levels, we stated we would not be able to gauge whether differences in labor costs are due to compensation or different levels of staffing. We further stated that collecting information on staffing levels allows the use of imputed labor rates from other sources (such as the Bureau of Labor Statistics). We also acknowledged the practical need to balance the burden involved in reporting extremely detailed staffing and labor costs information against the usefulness of detailed data for explaining variation in ground ambulance costs. Therefore, we proposed to collect information in the data collection instrument on the number of staff and labor costs for several detailed categories of response staff in Section 7 of the data collection instrument. This includes medical staff such as EMT-basic, EMT-intermediate, and EMT-paramedic, a single category for paid administrative and facilities staff (for example, executives, billing staff, and maintenance staff), and a single category for medical directors. We stated we believed this approach involves less respondent burden compared to reporting on each individual staff member. If more detailed categories were used for reporting staffing levels and costs, we stated we believed the burden involved in assigning paid administrative and facilities staff with multiple roles to individual categories or apportioning their labor and costs to separate categories would increase.

We stated that the main limitation of our approach is that we would not collect detailed information on specific paid administration and facilities labor categories. Therefore, we also proposed to collect some information that would help explain variation in labor costs by asking whether the ground ambulance organization has some staff in more specific paid administration

and facilities categories such as billing, dispatch, and maintenance staff (Section 7, question 1). We stated this question serves as a screening question to determine which response options appear to the respondent in several other questions in this section of the data collection instrument. We also proposed to ask for information on why individual labor categories are not used (Section 7, question 1) and if there is at least one individual with 20 hours a week or more of effort devoted to specific activities such as training and quality assurance (Section 7.2, question 2).

Reporting Staffing Levels

In reporting staffing levels in the data collection instrument, we stated that we considered several approaches. One approach we considered was asking the respondent to report only the number of staff (that is, counts of people). Under this approach, a part-time employee would count as “1” to the number of staff even if they worked a small number of hours per week. We stated we believed this approach would result in less accurate reporting of labor inputs, especially from organizations relying heavily on part-time staff or staff with responsibilities unrelated to ground ambulance services. We also considered allowing respondents to report full-time-equivalent (FTE) staff on a 40-hour per week basis, but ground ambulance organizations informed us that reporting FTEs would be burdensome. As a third approach, we considered asking respondents to report ground ambulance staffing levels in terms of hours over a reporting year. We stated that reporting labor hours over the entire reporting year allows for more accurate reporting of staff working part-time and may involve less burden for respondents that already tally annual labor hours (for example, via payroll records), but would likely be difficult for those who do not already track labor hours in this manner. As a fourth approach, we considered asking respondents to report ground ambulance staffing levels in terms of hours worked during a typical

week. We stated that reporting staffing levels in terms of hours worked either over a reporting year or during a typical week allows detailed accounting of part-time staff and staff with ground ambulance and other responsibilities and involves fewer calculations and adjustments than reporting FTEs. We also stated that reporting in terms of hours over a typical week has the additional advantage of simplifying reporting for staff that start or stop work during the 12-month reporting period. We further stated that the main limitation of reporting staffing levels in terms of hours over a typical week is that the week that the respondent selects for reporting may not be generalizable to other weeks in the reporting period.

In the interest of minimizing reporting burden, we proposed to collect information on the number of staff in terms of hours worked over a typical week (Sections 7.1 and 7.2). The instructions in the data collection instrument asked respondents to “select a week for reporting that is typical, in terms of seasonality, in the volume of services that you offer (if any) and staffing levels during the reporting year.”

Scope of Reported Labor Costs

For the purposes of collecting information on labor costs, we proposed to define labor costs to include compensation, benefits (for example, healthcare, paid time off, retirement contributions, etc.), stipends, overtime pay, and all other compensation to staff. We referred to these costs as fully-burdened costs. We stated that some ambulance providers and suppliers track compensation but not benefits because another entity, such as a municipality, pays for benefits, and that the ability of these ambulance organizations to report fully burdened costs may be limited. We stated that despite this limitation and due to the importance of labor costs as a component of total ground ambulance costs that we believed information on fully burdened costs (Sections 7.1 and 7.2) must be reported so that all relevant ground ambulance transport costs are

collected. We stated that ground ambulance organizations selected to report data may need to implement new tracking systems or request information from other entities (such as municipalities) to be able to report fully-burdened labor costs.

Volunteer Labor

In the proposed rule, we stated that ground ambulance organizations have also informed us that a significant share of ambulance organizations rely in part or entirely on volunteer labor and that the systems and data available to track the number of volunteers and the time that they devote to ground ambulance services varies. We proposed to collect information on the total number of volunteers and the total volunteer hours in a typical week using the same EMT/response staff and administrative and facilities staff categories used elsewhere in the data collection instrument (Section 7.3, questions 1-5). We stated the although some suggested that assigning a value to volunteer labor hours may be important, the data collection instrument collects information only on the amount of volunteer labor (measured in hours in a typical week) and not a market value for that labor. We also stated that we believed reported hours can be converted, if necessary, to market rates using data from other sources. We proposed to collect the total realized costs associated with volunteer labor such as stipends, honorariums, and other benefits to ensure all costs associated with ground ambulance transport are collected (Section 7.3, question 6).

Allocation and Reporting Staff with Other Non-Ground Ambulance Responsibilities

Since firefighter/EMTs are common in many ambulance suppliers, we proposed to ask respondents that share costs with a fire or police department to report total hours in a typical week for paid EMT/response staff with fire/police duties only (Section 7.1). In the proposed rule, we stated we believed this information could be used to subtract a portion of associated

labor costs when calculating ground ambulance labor costs. We stated we believed our approach is more consistent and involves less burden than asking respondents to perform their own allocation calculations necessary to report only the hours or full-time equivalents related to ground ambulance services.

As already noted, many ground ambulance organizations have staff with responsibilities beyond ground ambulance and fire/police response. To account for these scenarios, we proposed to ask respondents to report the total hours in a typical week unrelated to ground ambulance or fire/police response duties (which are addressed separately as described in Section 7.1), as the costs associated with this labor can be subtracted by those analyzing the data when calculating ground ambulance labor costs. We stated we believed this approach provides both transparency and consistency in the data with minimal burden, and may avoid scenarios where all of the costs associated with staff with limited ground ambulance responsibilities contribute to total ground ambulance costs.

We received comments on collecting data on collecting labor costs. The following is a summary of the comments we received and our responses.

Comment: All commenters supported the collecting of information on staffing and labor costs. They stated that they agree that labor is a major driver of the cost of ground ambulance services; thus, despite the fact that it may be difficult for some organizations to report full labor-related costs, they should be encouraged to do so to allow CMS and others to understand the full cost of labor, including compensation, benefits (for example, healthcare, paid time off, retirement contributions, etc.), stipends, overtime pay, and all other compensation to staff.

Commenters also stated that understanding and accounting for volunteer hours is an important component of ground ambulance costs and that they agree with our proposals to

collect information on the total number of volunteers and the total volunteer hours in a typical week using the same EMT/response staff and administrative and facilities staff categories used elsewhere in the proposed data collection instrument, as well as the decision to collect only hours and allow those analyzing the information from the data collection instrument to use appropriate proxies for placing a value on the cost of volunteer labor. Additionally, they stated that they support the CMS proposal to have respondents who also provide fire or public safety services to report the hours of their EMTs in a manner that will allow those using the data to subtract the portion of the associated labor costs that is not attributable to ground ambulance labor costs. They stated that the data collection system must ensure that the costs used to assess Medicare payment rates are specific to the provision of ground ambulance services and not mixed with the costs associated with other services that an organization might provide.

Several commenters made specific recommendations related to the definitions used in this section of the data collection instrument. Some commenters were concerned that the instruction to exclude staff and labor costs related to staff with responsibilities in “healthcare delivery unrelated to ground ambulance” could be interpreted to include EMT and other response staff arriving on the scene via a vehicle other than a ground ambulance. Another commenter asked that CMS clarify the scope for costs related to volunteer labor “stipends and/or benefits”.

Several commenters made specific recommendations related to improving the instructions for this section of the survey. One commenter expressed concern that CMS may be biasing certain reported staffing and cost information by asking respondents to categorize staff based on their roles or certification at the start of the reporting period. Other commenters requested clarification on how to report information for staff who work in both response and administrative roles. One commenter requested clarification on how respondents should select a

“typical week” over which staffing levels should be reported and recommended replacing the typical week approach with an approach based on dividing hours worked annually by 52. The same commenter also requested clarification on how the labor costs associated with medical directors should be reported and recommended separate reporting on staffing and costs for medical directors who are employees and those who are contractors. Another commenter requested clarification about the reporting of hours for volunteers who might be on call with pagers.

Some commenters suggested adding additional items to capture more information on how labor from partner organizations (that is, other entities sending response and other staff to respond to calls for service) contribute to overall responses. One commenter specifically suggested that CMS ask for counts of total staff for different types of responses so that CMS can better understand different staffing and deployment models.

Several commenters stated that throughout the proposed rule, CMS mentioned their intention to calculate the value of services performed by volunteer personnel by benchmarking their number of hours served against the average wage data collected by the Bureau of Labor Statistics. They stated that the Bureau of Labor Statistics’ current processes for gathering wage information for EMS personnel is inaccurate as it pertains to cross-trained firefighter/EMTs and firefighter/paramedics. Another commenter suggested using another database called Independent Sector to determine the value of volunteer labor.

Response: We thank commenters for their support. We considered several alternatives when developing our proposals for collecting information on staffing and labor costs, including approaches that would have allowed respondents to split reported hours and labor costs across multiple staff categories for individual staff with multiple responsibilities. While these

alternatives could collect more detailed information, they would all increase response burden substantially. The proposed instructions ensure that all compensation costs are reported, and no compensation costs are double counted. The instructions accomplish this by aiming to direct respondents to assign each individual staff member to only one labor category. While CMS recognizes the instructions are lengthy, the aim is to minimize necessary calculations and complex data tracking by the respondent.

It appears that several commenters mistakenly assumed that we proposed to collect compensation costs over a typical week rather than over the entire annual reporting period. While we did propose to collect information on staffing levels over a typical week, the data collection instrument collects compensation costs only on an annual basis. Collecting annual compensation minimizes some of the concerns raised by commenters related to under or over-estimating labor costs in a particular category. The distinction between reporting *staffing levels* during a typical week and labor costs over the entire year may have introduced unnecessary complication, and therefore, we are removing the instruction to report staffing levels during a typical week and instead will ask respondents to report staffing levels in terms of hours over the entire annual reporting period.

The proposed data collection instrument instructions ask respondents to report costs associated with contracted medical director services in Section 11 of the data collection instrument as an “other cost.” We agree with commenters that separating questions related to medical directors is confusing particularly given the fact that contracted medical directors are so common.

In reporting the hours associated with volunteer labor, it was not our intention to capture hours on-call while volunteers are at other locations or jobs. We intended to capture the hours in

service, which includes the time from which they receive a call or a page to the time they are finished with their call, as well as time spent in the station house performing duties as if they were being paid.

We agree that it would be possible to collect information that would help explain differences in staffing and deployment models, although collecting this information would add additional burden on respondents. The current labor questions collect what we believe is the most relevant information to assess how differences in labor inputs drive total costs – more specifically, the data collection instrument collects information on the total staff and total compensation. We agree that it is important to understand the extent to which other organizations contribute to responses, for example by providing paramedic or other staff to responses that are not paid by the organization submitting data. While the proposed data collection instrument collects costs related to these arrangements when a payment is made, the proposed data collection instrument does not otherwise collect information on when such arrangements exist, which we agree would be helpful information to include in the data collection instrument.

Comment: One commenter stated that using the Bureau of Labor Statistics is one method of valuing volunteer labor but provided an alternative method for valuing volunteer labor using Independent Sector data. Another commenter stated that the BLS' current processes for gathering wage information for EMS personnel is inaccurate as it pertains to cross-trained firefighter/EMTs and firefighter/paramedics. Commenters also stated that the definition of stipends and benefits for volunteer labor should be broadened to include all forms of compensation from the ground ambulance organization such as insurance, stipends, or other forms of compensation.

Response: We did not specify the use BLS or any other source of wage data to determine the valuation of volunteer labor in the proposed rule in order to provide flexibility in valuing volunteer labor when analyzing the data. The data collection instrument collects information on volunteer hours and total compensation of any type from the ground ambulance organization so we agree that the definition of “stipends and/or benefits” should be broadened to include all forms of compensation from the ground ambulance organization such as insurance, stipends, or other forms of compensation.

After consideration of the comments, we are removing the instruction to report staffing levels during a typical week and instead will ask respondents to report staffing levels in terms of hours over the entire annual reporting period. This will result in reporting instructions that are more similar for staffing levels and labor costs. We are not changing the instructions that ask respondents to categorize each staff member in only one category. While alternative approaches could collect more accurate and detailed information, we believe these alternatives would involve significant additional burden. We are adding new items to the labor section asking (1) whether another organization provides staff in certain labor categories (including paramedic, other EMT, and other) to responses where the sampled ground ambulance organization would transport the patient, and (2) what share of responses involve labor from other organizations in these categories. We believe these additions will help CMS understand when reported labor costs may be lower due to contributions to responses from other organizations.

To minimize confusion and potential double-counting of costs associated with medical directors, we are moving the specific question related to contracted medical director service costs from the other costs section, Section 11, to the labor section, Section 7, in the data collection instrument. We are editing the definition of “stipends and/or benefits” in relation to volunteer

compensation to include all compensation provided by the ground ambulance organization.

Organizations should only report the costs they pay for a medical director, not an estimated true cost for the value of that medical director's labor. We will also clarify the instructions surrounding the calculation of volunteer hours to include time spent in service for all volunteers. We are also editing the instructions in this section to clarify that staff participating in ground ambulance responses should be included regardless of how they arrive on the scene.

(ii.) Collecting Data on Facility Costs

Facility costs may include rent, mortgage payments, depreciation, property taxes, utilities, insurance, and maintenance, and the associated costs vary widely across ambulance providers and suppliers. Some ground ambulance organizations own facilities while for others, rent, mortgage, or leasing is an important component of total operational costs. Some ground ambulance organizations share facilities with other operations (such as fire and rescue services), and individual ground ambulance organizations often operate out of several facilities of different types, sizes, and share of space related to ground ambulance operations.

In the proposed rule, we considered requiring respondents to report facility costs aggregated across all facilities. We stated we believed this approach would minimize burden on the respondent by eliminating the need to break costs down by facility but that it may also increase the risk for inconsistencies in how respondents report total facilities costs. We stated that under this approach, respondents whose ground ambulance organizations share operational costs with a fire department or other entity would need to calculate and report an estimate of facilities costs that was relevant only to ground ambulance services.

We also considered requiring respondents to report all costs on a per-facility basis. We stated we believed this approach would allow the most flexibility in reporting complex facility

arrangements from ground ambulance organizations operating out of multiple facilities. We further stated that this approach may also involve more burden, particularly for larger organizations, to report costs on a facility-by-facility basis, and many organizations do not track costs such as maintenance or utilities on a per-facility basis.

We proposed a hybrid approach involving both per-facility and aggregate reporting of different information. We stated that first respondents report the total number of facilities (Section 8., questions 1-2) and then indicate for each facility whether they paid rent, mortgage, or neither during the reporting period, total square footage, and share of square footage related to ground ambulance services (Section 8.1, question 3); second, respondents report their per-facility rent, mortgage, or annual depreciation (Section 8.2); and third, respondents report facilities-related insurance, maintenance, utilities, and property taxes aggregated across all facilities (Section 8.3).

We stated that we believe this approach allows for the collection of the information needed to calculate a total facilities cost related to ground ambulance services while avoiding a burden on respondents to calculate allocated facility costs. We stated that total insurance, maintenance, utility, and property tax costs can be allocated using reported square footage and shares of square footage related to ground ambulance services. We further stated that the approach requires respondents to provide both the square footage of each facility, and the share of square footage for the facility that is related to ground ambulance operations. We stated that we expect some ground ambulance organizations would have this information available and others would need to collect this square footage information to report along with facilities costs, but did not believe this information would will be difficult to collect.

We received comments on collecting data on facility costs. The following is a summary

of the comments we received and our responses.

Comment: Many commenters stated that they support the proposals related to facility costs and had no additional suggestions. One commenter requested further guidance on how ground ambulance organizations should interpret the percentage of their facility square footage directly attributable to ground ambulance services. They asked if CMS is just looking for the space used to park the ambulance and store EMS supplies, how ground ambulance organizations should categorize common spaces, and what portion of the chief's office should be designated as being attributable to ground ambulance services.

Response: We are not specifying a particular methodology for calculating the percent of square footage attributable to ground ambulance services, in order to reduce the burden on organizations who might have a particular method in place already. The instructions in Section 8 of the data collection instrument ask for the total square footage of the facility and the percentage of the facility related to ground ambulance services. The entire square footage of the facility should be reported in the first case.

After consideration of the comments, we provided additional examples for clarification on how a ground ambulance organization should report the percentage of the facility attributed to ground ambulance services in the data collection instrument.

(iii.) Collecting Data on Vehicle Costs

Section 1834(l)(17)(A)(ii) of the Act requires CMS to collect information on “the utilization of capital equipment and ambulance capacity.” We proposed to collect information on the number of ground ambulances and other vehicles related to providing ground ambulance services, as well as the costs associated with these vehicles to meet these requirements.

In the proposed rule, we stated that ambulance organizations operate ground ambulances, as well as other vehicles to support their ground ambulance operation, and some may have a variety of other vehicles that are associated with ground ambulance responses. We provided the example of a fire truck staffed with fire personnel cross-trained as EMTs that may respond with a ground ambulance to an emergency call. We stated that other vehicles might be used in responses and may be referred to as a non-transporting EMS vehicle, a quick response vehicle, a fly-car, or an SUV that carries a paramedic to meet a BLS ambulance from another organization during the course of a response.

We considered two alternatives for collecting vehicle costs in the proposed rule. One alternative was to only include the costs for ambulances and exclude other certain non-ambulance response vehicles from reported costs. We stated that we believe that excluding other certain non-ambulance response vehicles from reported costs could potentially result in underreporting of total ground ambulance costs, particularly among those providers or suppliers that rely heavily on these vehicles to support their ground ambulance services. Another alternative we considered was to include the costs of all vehicles that are used as part of ambulance services, such as quick response vehicles that are used to supplement ambulances.

For all vehicles, vehicle costs can be reported either in aggregate or on a per-vehicle basis. We stated that we believe that while reporting vehicle costs in aggregate may involve less burden for some respondents, those respondents that do not track aggregated costs would still require a tool to enter information on per-vehicle basis. Furthermore, we stated we believed that aggregated costs for vehicles other than ground ambulances offer analysts with fewer alternatives to allocate a share of vehicle costs to ground ambulance services.

We proposed to collect data on vehicle costs in the data collection instrument in two parts: ground ambulance vehicles (Section 9.1); and all other vehicles related to ground ambulance operations (Section 9.2). For ground ambulance vehicles, we proposed to collect information on the number of vehicles, total miles traveled, and per-vehicle information on annual depreciated value (and remounting costs if applicable) for owned vehicles, and annual lease payments for rented vehicles (Section 9.1, questions 1-4). We considered proposing to collect the necessary information to calculate annual depreciated value using a standardized approach. However, we proposed to allow respondents with owned vehicles to use their own accounting approach to calculate annual depreciated value per vehicle. We stated we believed that allowing flexibility for respondents to use their standard approach for this calculation would result in more accurate data and less reporting burden.

We also proposed to use a similar approach to collect per-vehicle information for owned and leased vehicles of any other type that contribute to ground ambulance operations, including fire trucks, quick response vehicles, all-terrain vehicles, etc. (Section 9.2, questions 1-5). We stated that the proposed instructions in Section 9.2 of the data collection instrument specified that reported vehicles must support ground ambulance services. We proposed to collect the type of each vehicle in broad categories in addition to the annual depreciated value or lease payment amount for each vehicle.

In addition to the above costs, we also proposed to collect aggregate costs associated with licensing, registration, maintenance, fuel, insurance costs for all vehicles combined (ambulance and non-ambulance) (Section 9.3, questions 1-5). We stated we believe that these costs are often aggregated within providers' and suppliers' records and that reporting in aggregate form may reduce respondent burden with minimum risk for reporting error.

When estimating total ground ambulance vehicle costs for ground ambulance organizations that share operational costs with fire and police response or other non-ground ambulance activities, we stated that a share of vehicle costs reported via the data collection instrument will need to be allocated as vehicle costs related to ground ambulance services. One alternative we considered to do this was simply to ask respondents about the share of costs associated with ground ambulance services as we thought this would be the least burdensome approach; however, we stated that we believed data collected in this manner would not allow for estimation of costs associated with non-ground ambulance vehicles that support ambulance services. We considered another alternative where (1) the ratio of ground ambulance to total responses would be used to allocate costs associated with non-ambulance vehicles, (2) the total number of vehicles would be used to allocate aggregate costs associated with licensing, registration, maintenance, and fuel costs, and (3) depreciated annual costs and/or lease payment amounts would be used to allocate insurance costs. We stated that the main limitation of this approach is that maintenance and fuel costs could vary significantly across vehicle categories. We provided the example that maintenance and fuel costs may be significantly different for ground ambulance than for other types of vehicles. As a result, we proposed a modification of this alternative where we also ask respondents to list percent of total maintenance and fuel costs attributable to each type of vehicle (that is, ground ambulances, fire trucks, land rescue vehicles, water rescue vehicle, other vehicles that respond to emergencies such as quick response vehicles, and other vehicles; Section 9.3, questions 4 and 5). We proposed to also ask respondents to report total mileage for ground ambulance (land and water separately) and total mileage for other vehicles related to ground ambulance responses (land and water separately) as a potential alternative means to allocate fuel and maintenance costs.

We received comments on collecting data on vehicle costs. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that they generally support the approach to collect vehicle cost data. Many commenters stated that they agree it will be easier for ground ambulance organizations to track their total vehicle costs and report that information than try to allocate the vehicle costs between “loaded” (or response) hours/miles and the costs incurred when the vehicles are not being used to respond directly to a request for service (for example, a 911 call). They stated that this approach would work across the major cost centers outlined in the proposed rule. They stated that they understand that CMS has sought to strike a balance between asking for detailed information and not imposing an overwhelming burden on ground ambulance organizations. They stated that while they believe it may overstate the costs to aggregate those associated with licensing, registration, maintenance, fuel, insurance costs for all vehicles combined, both ambulance and non-ambulance, they appreciate the interest in reducing the burden on respondents when reporting such information. They stated that they also support differentiating between vehicles that function as ground ambulances and those that do not. They requested clarification on whether the definition of a ground ambulance refers to the CMS definition or to the definitions that apply in the respondent’s state or locality. One commenter suggested adding more general examples of non-ambulance vehicles.

One commenter requested clarification about how to handle the reporting of fire trucks specifically, in cases where a fire truck with EMS personnel may be sent to the scene as part of a response. This fire truck could be owned by the organization filling out the survey, or another non-transporting fire truck from a different organization. This same commenter also requested clarification on how to report insurance costs when these may be paid by another agency, such as

a state agency that purchases insurance on behalf of all of the vehicles in its fleet.

Response: We agree that it is important to balance burden on respondents with the level of detail of vehicle data reported in this section. While some data, for example licensing, registration, maintenance, fuel, insurance costs, could be collected in more detail in relation to ground ambulance services, we believe that alternatives to collect more detailed data would involve significant additional burden. Our intention is for organizations to report the ambulances that qualify as such in their jurisdiction. We expect that most of these ground ambulances would meet CMS' definition of a ground ambulance.

It is our intention in the vehicles section to collect data on the costs of vehicles associated with the reporting organization only. This may include fire trucks if the fire trucks are sent to the scene with EMS personnel. If there are no firefighters co-trained as EMS personnel, then these fire trucks are not related to ground ambulance service and should not be included. If an organization is assisted by another organization at the scene (such as from a different fire department), the costs associated with these vehicles would not be included. We state elsewhere in these comments that we will add an additional question to the miscellaneous costs that allows organizations to report fees paid to other non-transporting organizations for their services. We believe that it would be too much additional burden to ask organizations to assess the costs of providing services for organizations other than their own.

For insurance, fuel or other vehicle-related costs, we ask that organizations ask the agency providing these items for an estimate of their cost.

After consideration of the comments, we added more general examples of non-ambulance vehicles, such as sport utility vehicles and pickup trucks used to support ground ambulance services, which should be included in reporting in this section. We also clarified in the data

collection instrument that respondents should report on all ground ambulance vehicles that meet local and state requirements.

(iv.) Collecting Data on Equipment and Supply Costs

In our interviews with ground ambulance organizations, we were told that not all ground ambulance organizations would be able to report detailed item-by-item equipment and supply information, and that some organizations have far more sophisticated inventory tracking systems than others that would allow them to report detailed information within a category.

In the proposed rule, we stated we considered alternative approaches related to reporting equipment and supply costs that varied primarily on the level of detail for reporting. We considered extremely detailed data reporting as it would be potentially useful to identify variability in costs across organizations. However, as noted above, we stated that many ground ambulance organizations may not keep detailed records of all their individual equipment and supply costs. Taking those factors into account, we proposed to request total costs in a small number of equipment and supply categories rather than itemized information for all equipment and supply categories (Section 10). We stated these would include:

- Capital medical equipment.
- Medications.
- All other medical equipment, supplies, and consumables.
- Capital non-medical equipment.
- Uniforms.
- All other non-medical equipment and supplies.

We also considered whether to have respondents report both medical and non-medical equipment and supplies together. We stated that we believed that the majority of medical

supplies are more likely to be related to ground ambulance services than non-medical supplies for organizations with shared services, and therefore, we proposed to collect this information separately.

Reporting of Capital versus Non-Capital Equipment

To meet the requirement in section 1834(l)(17)(A)(ii) of the Act to collect information to facilitate the analysis of “the utilization of capital equipment,” we proposed to separately collect information on capital equipment expenses (rather than equipment-related operating expenses). Capital equipment (both medical and non-medical) yield utility over time, which we stated can vary depending on the expected service life of the specific good. We stated that in addition to the cost of purchasing or leasing durable goods equipment, depreciation and maintenance costs must be considered in the total cost calculations. Since ground ambulance organizations often track capital equipment on an itemized level, separating items of significantly different age and cost is necessary to calculate depreciation. Therefore, to minimize burden by aligning reporting with the accounting approaches used by respondents, we proposed to ask for capital (Section 10.1, question 1; Section 10.2, question 1) and non-capital costs (Section 10.1, questions 2-3; Section 10.2, questions 2-3) separately so that respondents could report annual depreciated costs for capital equipment and total annual costs otherwise. We also proposed to allow respondents to report annual maintenance and service costs for capital equipment because ground ambulance organizations have stated during interviews that these costs can be significant compared to purchase costs or annual depreciated costs. Finally, we proposed to allow respondents to use their own standard accounting practice to categorize equipment as capital or non-capital. We stated that while we believe it would be possible to ask respondents to use a standard approach,

we believed this would require respondents with another practice to recalculate annual depreciated cost and potentially increase respondent burden and reporting errors.

Allocation of Shared Costs

During interviews with ground ambulance organizations, it was noted that although the vast majority of equipment and supplies are for ground ambulance services, some costs are shared with hospitals or clinics. We stated that we believed separate reporting on medical and non-medical equipment and supplies would facilitate allocation (Section 10.1, versus Section 10.2). For organizations that indicate the use of shared services, we proposed to ask separately what share of medical and non-medical equipment and supply costs are related to ground ambulance services (Section 10.1, questions 1c, 2a; Section 10.2, questions 1c, 2a, 3a). We stated the share of non-medical equipment and supplies used for ambulance services may vary for respondents with operations beyond ambulance services. While other allocation methods (such as the share of responses that are ground ambulance responses) may be appropriate to allocate equipment and supply costs, asking respondents to provide their estimate of the share of equipment and supply costs related to ambulance services reduces assumptions made about how best to apply allocation across the various equipment and supplies reported.

We received comments on collecting data on equipment and supply costs. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed a desire to work with CMS to develop additional categories for the cost of equipment, consumables, and supplies for future surveys that would allow policy-makers to address high-cost products or patients who require services resulting in higher costs. They stated that they support the differentiation between capital and non- capital equipment, as well as the proposed allocation rules, and questioned whether

nebulizers, which are devices for producing a fine spray of liquid for inhaling a drug, should be considered capital equipment. Another commenter stated that some organizations may not separately report medication costs from other supplies and equipment, and questioned why this was important to separate.

Response: While there are many other potential equipment and supply categories that could have been added separately to this section, in the interest of balancing the level of detail collected in the data collection instrument with burden, we decided to limit this section to only a small number of specific types of supplies and equipment (such as drugs) for which we proposed to collect costs separately. We believe that the data collected through the data collection instrument may point to opportunities for additional refinement in this section in future years of data collection. For example, rather than collect information on all drugs in aggregate, reporting by category of drug or even for individual drugs may provide useful information. Still, given the fact that information on ground ambulance costs is limited, we believe the appropriate first step is to collect higher-level cost information. We also agree with the commenters that items such as nebulizers should be considered non-capital equipment as they are typically a single usage device when used by ground ambulance providers and suppliers. In the process of developing the survey, we heard from many organizations about the increasing cost of medications and as a result, we requested these items to be reported separately. We recognize that some organizations may not be able to separate their drug costs from other medical consumables, so this question is optional on the survey.

After consideration of the comments, we removed the example of nebulizers from the capital equipment section.

(v.) *Collecting Data on Other Costs*

In addition to core costs for ambulance providers and suppliers that are associated with labor, vehicles, facilities, and equipment or supplies, ground ambulance organizations have indicated that these entities incur costs associated with contracted services (for example, for billing, vehicle maintenance, accounting, dispatch or call center services, facilities maintenance, and IT support), as well as other miscellaneous costs (for example, administrative expenses, fees and taxes) to support ground ambulance services.

In the proposed rule, we considered including contracted services as part of the labor section, since many of the contracted services related to costs that would otherwise be labor-related if the tasks were performed by employed staff. However, we were concerned that ground ambulance organizations might report this information in multiple data collection instrument sections (for example, both labor and miscellaneous costs). As a result, we separated contracted services into their own categories. While we considered allowing respondents to report in the aggregate any other miscellaneous costs associated with ground ambulance services because we stated we believed this approach may be less burdensome for organizations that track miscellaneous costs in aggregate, we stated we believed this would introduce a large amount of reporting bias and inconsistency in reporting across organizations. In the proposed rule, we made several proposals related to reporting contracted services and miscellaneous costs as described below.

Reporting Contracted Services

For contracted services, we proposed that respondents indicate whether their organization utilizes contracted services to support a variety of tasks (Section 11, question 1), the associated total annual cost for these services, and the percentage of costs attributable to ground ambulance

services. The data collection instrument provided instructions to ensure that respondents do not report on contracted costs multiple times.

Reporting of Miscellaneous Costs

For other miscellaneous costs not otherwise captured in prior sections of the data collection instrument, we proposed that respondents be able to report additional costs first using an extensive list of other potential cost categories (Section 11, question 2) and then use write-in fields if necessary. We stated that providing a pre-populated check list would help ensure the consistency and completeness of reporting across respondents.

Allocation of Miscellaneous Shared Costs

Information from ground ambulance organizations indicates that there are a number of miscellaneous costs associated with the overall operation of organizations that are shared across services. To account for these shared costs, we proposed that respondents report an allocation factor for each contracted service, (Section 11, question 1), as well as for each reported miscellaneous expense (Section 11, questions 3-4) as described in the data collection instrument. We considered the alternative of asking for an overall share of miscellaneous costs associated with ground ambulance services or utilizing information gathered about the share of ground ambulance responses versus total responses to determine an overall allocation factor. We stated that while this would present less burden on respondents, the share of miscellaneous costs and share of contracted services varies widely across organizations with shared services.

We received comments on collecting data on other costs. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed data elements for other costs, but as noted with regard to labor, they requested clarification as to the allocation of medical director

fees to ensure there is no double-counting between the two sections.

Several commenters stated that Section 11, Question 3 (advertising expenses) of the data collection instrument directs respondents to provide information on a variety of general and miscellaneous costs. They stated they believe CMS should clarify what is meant by the “Advertising” category of expenses because it is unclear whether this is generic advertising to the public or if this would be inclusive of advertising conducted in order to recruit volunteer personnel. Additionally, they thought CMS should clarify which advertising expenses this includes (print, television, radio, online/social media, trade show exhibitions, promotional items such as shirts and stickers, etc.).

Another commenter suggested that CMS collect information about unpaid transports (excluding charitable care) and/or uncompensated health care services when no transport is involved. They stated that they recognize that Section 5 in the data collection instrument asks about the volume of paid transports. They stated that it is not clear that information about the actual costs associated with unpaid transports could be determined through the other questions at this time but that this information is essential to understand how the limitations in the current Medicare benefit have a negative impact on overall Medicare costs. They also stated that this information would also help policy-makers assess how unpaid services could be addressed in the future. They stated that they believe that this information should be distinguished from bad debt or charitable care, because the former implies the inability to collect coinsurance amounts, while the latter indicates services provided to those without insurance or funds to pay for the services. This unpaid category would be focused on transports or services provided to patients with insurance, but for which the insurance company refuses to pay.

One commenter suggested that costs for franchise fees needed to be collected in the

survey because franchise fees are costs some organizations pay local governments to operate within the jurisdiction. The same commenter advised that dispatch costs would be difficult to capture for rural organizations because dispatch services are generally run by a central entity such as county government. Finally, one commenter requested clarification on what was included in ‘total costs’ and ‘total revenues’ as to whether this included total costs and revenues from organizations with shared services.

Response: As noted in our response to comments in the labor section, we are moving the reporting of contracted medical director services to the labor section to avoid potential confusion and double-counting. More generally, the proposed data collection instrument included an instruction in the contracted labor section to not report funds that had already been reported elsewhere in the survey. We agree with the comment suggesting clarifications to the definition of advertising. While the proposed data collection instrument collects some information relevant to uncompensated care, we did not intend to directly collect respondents’ estimates of uncompensated care. The data collection instrument does collect information on the total costs borne by the ground ambulance organization, including costs related to transports for which no or partial payment is received. The data collection instrument also collects information on the total number of transports for which payment is received versus total transports.

In response to the suggestion to add a question to collect information on franchise fees, we wanted to highlight that this data item is already being collected in the section on other costs, which reads as follows: “Fees paid to local jurisdictions required as condition of providing ground ambulance service.”

We intended the total costs and total revenues to incorporate the full totals for each question. This means that for organizations with shared services, they would report their full

operating and capital costs, and revenues, even for the portions of their business unrelated to ground ambulance service. For example, a fire department also operating an ambulance service would answer this question with their total cost and total revenue across the whole organization. For organizations without shared services, their total costs will match those reported in the data collection instrument. For organizations with shared services, their total costs will be higher than those reported in the data collection instrument.

After consideration of the comments, we clarified the definition of advertising to include any type of advertising (even for recruiting purposes) in any medium (print, radio, internet, etc.). We also added additional clarification to the questions for total costs and total revenues.

d. Data Collection on Revenue

Section 1834(l)(17)(A) of the Act requires the development of a data collection system to collect revenue information for ground ambulance provider and suppliers. Payments from Medicare and other health care payers are important components of total revenue for some ambulance providers and suppliers. Most ambulance providers and suppliers also have other sources of revenue in addition to payments for billed services. Based on review of existing literature and discussions with ground ambulance organizations, these primary sources of revenue include, but are not limited to: patient out-of-pocket payments; direct public financing of fire, EMS, or other agencies; subsidies, grants, and other revenue from local, state, or federal government sources; revenue from providing services under contract; and fundraising and donations. In the proposed rule we stated that we view total revenue as the sum of payments from health care payers and all other sources of revenue, including those listed above.

We stated that while collecting information on total revenue is essential to understanding variations in how EMS services are financed across the country, this information is not collected

by Medicare or by any other entity of which we are aware. Similar to other sections of the data collection instrument, we stated that we also considered what level of data to request in this section. We proposed to ask for total revenue in aggregate (Section 13, question 1) and total revenue from paid ground ambulance transports for Medicare and, if possible, broken down by payer category for other payers (Section 13, questions 2-5). We proposed this level of detail because we believe understanding payer mix would be helpful to assess Medicare's contributions to total revenue. We stated that based on information provided by ambulance providers and suppliers, there is variation in how patient-paid amounts were recorded in ambulance billing systems. We proposed to ask respondents whether revenue by payer includes corresponding patient cost sharing or whether cost-sharing amounts are included in a self-pay category. For other revenue (for example, contracts from facilities and membership fees (such as those associated with community members that enroll in ambulance clubs), we proposed to request information on additional revenue in predetermined categories and using write-in fields if necessary (Section 13, question 5).

Allocation of Shared Revenues. Ground ambulance organizations vary widely in the types of other revenue sources (as noted in Section 13, question 6) they receive and their share of allocated costs. For this reason, we proposed to have respondents report the share of revenue for each category that is attributable to ground ambulance services (Section 13). Similar to miscellaneous costs, we considered the alternative of asking for an overall share of other revenue sources associated with ground ambulance services or utilizing information gathered about the share of ground ambulance responses versus total responses to determine an overall allocation factor. While this would present less burden on respondents, we stated that we did not believe it

would adequately capture the revenue only associated with ground ambulance services, especially for organization with shared services.

To collect information on uncompensated care, including charity care and bad debt, we proposed to collect information on both total and paid transports. We stated these two measures of volume can be used to provide insight into the share of transports that are not paid. The data collection instrument broadly collects information on total costs (including costs incurred in furnishing services that are ultimately paid and not paid) and total transports (again including transports that are both paid and not paid). We stated that the collected data could be used to estimate per-transport costs that can be estimated by dividing total costs by total transports, so we do not believe it is necessary to directly collect information on uncompensated care in the revenue section of the data collection instrument.

We invited comments on collecting revenue. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the collection of ground ambulance revenue from different types of payers, as well as the collection of other sources of revenue. These commenters asked that CMS divide Medicaid revenue by traditional Medicaid and Medicaid managed care, similar to the separate lines for Medicare fee-for-service and Medicare Advantage and recommend that CMS define the term “ambulance club,” which they stated is not a standard term.

Several commenters asked CMS to add a revenue category to Section 13, Question 5 in the data collection instrument to collect in-kind contributions (including labor, supplies, medications, etc.) provided by another agency which responds to calls for emergency service in conjunction with the ground ambulance organization completing the data collection instrument.

Commenters would like respondents to select yes or no, enter the dollar amount, and enter a percentage. They stated that fire departments often provide EMS care to patients, including at the ALS level, even when another agency provides the actual ground transportation services to a patient and when this occurs, the fire department's ALS personnel often continue providing patient care inside the third-party ambulance during transportation to the hospital. They stated that this continuation of patient care by fire department personnel constitutes a significant savings to the third-party transportation company as they do not incur the costs associated with the fire department employee(s) such as salary, benefits, and insurance. They also stated that in many cases, the fire department never receives reimbursement for these costs by the third-party ground ambulance agency. They stated that since the data collection instrument only will apply to Medicare-enrolled ground ambulance agencies that they believe that the data collection instrument should count these services as in-kind contributions to the third-party ambulance agency. Commenters further stated that ground agencies selected for sampling by CMS each year can easily gain this information by requesting it from the agencies which commonly respond to calls for emergency service with the third-party ground ambulance agency.

Several commenters stated that Section 11, Question 5 seeks information from respondents on several revenue categories which may apply to an ambulance supplier or provider. They stated that since the goal of the data collection instrument is to assess the adequacy of CMS' reimbursements for the cost of providing patient care, they believed that the inclusion of tax revenue for public agencies could lead to the inclusion of unrelated data. They stated that operating revenue that is derived from taxation and provided to public agencies represents the level of service expected by a community but is not expected to be a dollar-for-dollar coverage of patient care costs and that these funds should supplement, not supplant, CMS'

reimbursements to public agencies for the care that they provide to Medicare beneficiaries. They also stated that they believed that tax-derived subsidies should be reported by respondents when these funds are included in a larger contract between a local government and a private entity. They stated that in these cases, these subsidies are intertwined with the overall structure and terms of the contract but that they do support the requirement for respondents to report when revenue is received by any agency (public or private) through an EMS-specific tax and as a result, they recommend that CMS adopt changes to Section 13, question 5.

Another commenter suggested that donations to organizations that support volunteers should be considered in the revenue section. This same commenter also requested clarification as to whether patient self-pay includes the uninsured or uncovered transports.

Response: We agree that it would be informative to distinguish between traditional FFS Medicaid and Medicaid managed care revenue and will add that option to the instrument. We use the term ‘ambulance club’ to describe a membership organization where local residents pay a regular fee for ambulance service not provided by their local governments. We do not agree with the commenter suggesting to collect information on the in-kind subsidies provided by other, non-transporting agencies who assist the reporting organization at the scene or while transporting patients. We believe this additional question will add substantial burden for organizations who must collect it, as this requires valuing the other organization’s labor, supplies, vehicles, facilities, etc., and this information will be captured in the cost sections if there is a contract between the organizations for reimbursement.

The data collection instrument is designed to capture the costs of operating a ground ambulance service, consistent with our statutory requirements and we do not believe that including donations to other organizations would be appropriate to include. Donations, payment,

or benefits made by other entities that support staff or other services that are out of scope for this data collection are also out of scope when reporting revenue. The patient self-pay revenue section is intended to capture payments patients made to the ambulance organization for a transport that was covered or not covered by their health insurer.

We are required to collect information on revenue received by ground ambulance organizations. Therefore, we do not agree that tax revenue for public agencies should be excluded from the data collection instrument because omitting questions related to this source of revenue from that data collection instrument would result in an incomplete picture of revenue across different types of ground ambulance organizations. The data collection instrument collects information separately on tax revenue for public agencies and from contracts between local governments and ground ambulance organizations.

After consideration of the comments, we clarified the meaning of an ambulance club and added an option to separately report Medicaid Managed care revenue. We also added an option to separately report contract revenue from local governments, as well as tax revenue from local governments, and clarified that self-pay refers to non-covered transports.

After consideration of the comments regarding the data collection instrument, we are finalizing our proposals regarding the format, scope, costs and revenue with several modifications or clarifications as described in the sections above.

5. Final Policies for Sampling

Section 1834(l)(17)(B)(i) of the Act requires that CMS identify the ground ambulance providers and suppliers organizations that would be required to submit information under the data collection system, including the representative sample. Section 1834(l)(17)(B)(ii)(II) of the Act requires the representative sample must be representative of the different types of providers

and suppliers of ground ambulance services (such as those providers and suppliers that are part of an emergency service or part of a government organization) and the geographic locations in which ground ambulance services are furnished (such as urban, rural, and low population density areas). Under section 1834(l)(17)(B)(ii)(III) of the Act, the Secretary cannot include an individual ambulance provider and supplier in 2 consecutive years, to the extent practicable. In the proposed rule, we stated that in addition to meeting the requirements set forth in the statute, including developing a representative sample, our proposals around sampling aim to balance our need for statistical precision with reporting burden. We also stated that our we developed our proposals with the intention of obtaining statistical precision with the least amount of reporting burden.

Eligible Organizations. In the proposed rule, we stated that a sampling frame drawing on all ground ambulance organizations in the United States and its territories that provide ground ambulance services (that is, not just those enrolled in Medicare or billing Medicare in a given year) may be of interest conceptually, but that we have not identified a data source listing all ambulance providers and suppliers that could be used as the source for a broader sampling frame. Since sections 1834(l)(17)(A) of the Act requires the Secretary to collect cost, revenue, and utilization information from providers of services and suppliers of ground ambulance services (which are Medicare specific terms with specific meaning) with the purpose of determining the adequacy of payment rates and section 1834(l)(17)(D) of the Act requires the Secretary to reduce payments to ground ambulance organizations that do not sufficiently report, we stated we believe that the intent of the statute is to collect information under the data collection system from ground ambulance organizations that bill Medicare. Therefore, we proposed to sample ground ambulance organizations that are enrolled in Medicare and that billed for at least one Medicare

ambulance transport in the most recent year for which we have a full year of claims data prior to sampling. Since ground ambulance organizations have a full year to submit their claims to Medicare after the date of service, claims data for a calendar year are generally not considered complete until the end of the following calendar year. We stated that as a result, we would use 2017 Medicare claims and enrollment data to determine the sample for the 2020 data collection period because 2018 Medicare claims data could not be considered complete in late 2019 when the sample for the 2020 data collection period would be selected.

Sampling at the NPI level: Section 1834(l)(17) of the Act prohibits, to the extent practicable, sampling the same ambulance provider or supplier in 2 consecutive years. Although we stated we considered sampling at a broader parent organization level for those that bill Medicare under more than one NPI, we stated we found it was difficult to tease out of the Medicare enrollment data all the complexities of the business relationships and identify all NPIs that may be affiliated with the same parent organization. Therefore, we proposed to select the sample at the NPI level and to include the specific NPI selected to report information.

Furthermore, we proposed to collect the name of the ground ambulance organization and the name and contact information of the person responsible for completing the data collection instrument for the purposes of confirming that the data submitted aligns with the intended NPI (Section 2, questions 3 and 4).

Organizations using volunteer labor: Some stakeholders have suggested that ground ambulance organizations relying on volunteer labor above a certain threshold (for example, more than 10 percent of volunteer labor) should be exempt from sampling. Others have suggested that ground ambulance organizations using volunteer labor should not be excluded because those organizations that use volunteer labor are likely to be smaller and that a large share of ambulance

suppliers (particularly those in rural and super rural areas) would be exempt from sampling, and therefore, our sample would not be representative as required by section 1834(l)(17)(B)(ii) of the Act. We acknowledged that analysis of the data may require additional steps to combine data submitted from ground ambulance organizations that do and do not rely on volunteers since reported labor costs would be significantly lower for ground ambulance organizations that use volunteer labor compared to those that do not. We stated that ground ambulance organizations that use volunteer labor might have some costs related to their volunteer labor, such as stipends, but may not have others, such as an hourly wage. Therefore, we proposed to collect information on paid and unpaid volunteer hours during a typical week using the same EMT/response staff categories used elsewhere in the data collection instrument. We stated we believed reported hours could be converted to market rates using data from other sources, such as the Bureau of Labor Statistics' wage data. Ambulance providers and supplies that rely on volunteer labor reported that it is becoming increasingly difficult to find volunteers and they are having to hire paid staff in their place, especially for the more costly labor categories, such as paramedics. Therefore, we proposed that ambulance providers and supplies that use any amount of volunteer labor be included in sampling. We invited comments as to whether organizations that rely on volunteer labor should be exempt from sampling.

Sampling file. We proposed several organizational characteristics for the specific strata (volume of Medicare billed transports, service area population density, ownership, provider versus supplier status, and the share of transports that are non-emergency) that we stated could be obtained from available Medicare data. We proposed to develop sampling files using the most recent full year of data available. For the first sample notified in 2019 and reporting in 2020, we proposed to use 2017 claims and enrollment data. Another alternative we considered was using

2018 data, however we did not propose this because such data may not be complete for all 2018 service dates at the time the sample for the initial year of data reporting is selected. We invited comments on our proposal to use the most recent full year of available Medicare data for sampling purposes, as described above.

Implications of historical sampling files. In the proposed rule we stated that we expect there may be instances in which some ground ambulance organizations that were in operation at the time they were selected for the sample may cease operations by the time data reporting begins and that we expect that some new ground ambulance organizations would start operating between the time the sample was created and when reporting begins. Since we proposed to collect a full 12 continuous months of data, these organizations would not have the data we proposed to collect. Therefore, we proposed that ground ambulance providers and suppliers organizations selected for the sample that were not operating for the full 12 continuous months of the data collection period would be exempt from reporting for the applicable data collection period; however, for newer ground ambulance organizations, they would be eligible for sampling and reporting in future years when they have a full continuous 12 months of data.

We stated that we believed the above scenarios are inevitable given the significant amount of time between sampling and data reporting and invited comments on our approach regarding exempting ground ambulance organizations who do not have a full 12-month continuous period of data.

Sampling rate: We proposed that 25 percent of ground ambulance organizations be sampled from all strata (as described below) in each of the first 4 years of reporting without replacement; that is, if an organization is sampled in Year 1, it would not be eligible for sampling again in the subsequent 3 years of data collection. We proposed a 25 percent sampling rate

because we stated if a lower sampling rate is used, estimates of cost, revenue, and utilization from the data collected via the data collection instrument for subgroups of ground ambulance suppliers will be of inadequate precision as described in the following section. We stated that our analyses illustrated that using a 50 percent sampling rate would yield only marginal gains in precision over a sampling NPIs at a 25 percent rate while doubling the response burden. We stated that in our view, these gains are not sufficient to merit the increased burden that would be imposed by implementing a higher sampling rate. We stated that our proposal was informed by analyses regarding the alternative sampling rates in Chapter 7 of the CAMH report. We invited comments on the sampling rate of 25 percent each year.

We also proposed to notify ground ambulance organizations that have been selected for the representative sample by listing such ground ambulance organizations on the CMS website at <https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html> and provide written notification to each selected ground ambulance organization via email or U.S. mail. We stated that notification on the CMS website would be provided at least 30 days prior to the time the selected ambulance organization would will be required to begin collecting data. For purposes of CY 2020, we stated that we would post such information on the website when the CY 2020 PFS final rule is issued. We also proposed to codify the representative sample requirements in § 414.626(c).

Approach for Sampling: In the proposed rule, we considered several alternatives for developing a stratified sampling approach to facilitate data collection from specific types of ground ambulance organizations. Section 1834(l)(17)(B)(ii)(II) of the Act requires that the sample be representative of the different types of providers and suppliers of ground ambulance services, such as those providers and suppliers that are part of an emergency service or part of a

government organization and the geographic locations in which ground ambulance services are furnished (such as urban, rural, and low population density areas). One approach we considered was sampling ground ambulance organizations in proportion to their volume of Medicare-billed ground ambulance services. Under this approach, we stated that organizations with more billed Medicare ground ambulance transports would be more likely to be sampled than organizations with fewer billed Medicare ground ambulance transports. The analysis of our 2016 data described in the CAMH report shows that a small number of ground ambulance organizations provided a large share of total Medicare transports. We stated that the top 10 percent of ground ambulance organizations by volume accounted for nearly 70 percent of total Medicare ground ambulance transports and the bottom 50 percent of ambulance providers and suppliers by volume accounted for only 3 percent of total Medicare ground ambulance transports. Under this approach, we stated that the ambulance providers and suppliers in the top 10 percent by volume would be much more likely to be sampled compared to those in the bottom 50 percent by volume. We also stated that while this approach would efficiently collect data on the majority of Medicare ground ambulance transports, we do not believe that this approach would comport with the requirements in section 1834(l)(17)(B)(ii)(II) of the Act to develop a representative sample of ground ambulance organizations based on the characteristics (such as ownership and geographic location) of ambulance providers and suppliers. Therefore, we stated that we do not believe that data we would be collecting using this approach would meet the requirements in section 1834(l)(17)(B)(ii)(II) of the Act.

Other alternatives for a sampling methodology we considered included simple and stratified random samples of ground ambulance organizations. We stated a simple random sample would include a fixed share of all ground ambulance organizations, regardless of any

differences in characteristics, in each year's sample. Unlike sampling in proportion to Medicare-billed ground ambulance services, we stated a simple random sample by definition provides a representative sample. A stratified random sample first stratifies all ground ambulance organizations based on selected characteristics and then a sample is selected at random from the strata. We stated the rate at which these organizations are sampled would be the same for organizations in the same stratum; however, that the sampling rate may vary across strata. So long as the sampling rate is not zero within any stratum and so long as appropriate weighting adjustments are used, we stated the sample would be considered representative.

As discussed in the proposed rule, stratified random sampling has several advantages in that it is easy to implement and it meets the requirement that the sample be representative and it also can be used to target sampling of ambulance organizations with specific characteristics, such as ownership and geographic location, to specifically meet the requirements in section 1834(l)(17)(B)(ii)(II) of the Act that the sample be representative of the different types of providers and suppliers of ground ambulance services, such as those providers and suppliers that are part of an emergency service or part of a government organization and the geographic locations in which ground ambulance services are furnished (such as urban, rural, and low population density areas). We stated that it is also possible to oversample from less prevalent strata using this approach in order to facilitate more precise estimates for certain groups or comparisons between subgroups. Furthermore, unlike a simple random sample, we stated the flexibility to vary sampling rates across strata allows the ability to account for anticipated and unanticipated rates of nonresponse.

We stated that we believe that use of a stratified random sample would comport with the statutory requirements. Therefore, we proposed a stratified random sample approach.

Specifically, we proposed to sample from each strata at the same rate (25 percent, as described above). We stated we believe that data collected from a sample of this type can be adjusted via statistical weighting to be representative of all ground ambulance organizations billing Medicare for ground ambulance services even if response rates vary across the characteristics used for stratification.

For the purposes of estimating the number of responses from the sampled ground ambulance organizations, we stated we assumed that all ground ambulance providers and suppliers organizations sampled will report, because: (1) reporting is a requirement; (2) there is a 10 percent payment reduction for failure to sufficiently report; and (3) we believed every ground ambulance organization would want its data accounted for in the evaluation of the extent to which reported costs relate to payment rates.

Variables for Stratification: Section 1834(l)(17)(B)(ii)(II) of the Act requires that the sample be representative of the different types of providers and suppliers of ground ambulance services, such as those providers and suppliers that are part of an emergency service or part of a government organization, and the geographic locations in which ground ambulance services are furnished (such as urban, rural, and low population density areas). We proposed a stratified sampling approach under which we would first sample based on a set of characteristics of ground ambulance organizations that are described below (that is, strata) and then assess response rates based on those characteristics. Based on our analysis of information provided by ground ambulance organizations, we stated we believed there are several important characteristics that vary among ground ambulance organizations that have implications for their costs and revenues and that could serve as strata for the purposes of sampling:

- *Provider versus supplier status.* The GAO (2012)⁹⁷ and HHS (2015)⁹⁸ reports found much higher per-transport costs for ambulance providers than those of ambulance suppliers. We stated this suggests that the ground ambulance cost structures for ambulance providers and suppliers are fundamentally different.

- *Service area population density.* Ground ambulance organizations operate in urban, rural, and super-rural settings. As described in the CAMH report, rural and super-rural organizations tend to be smaller, transport patients at greater distances, are more likely to be government owned, and rely more heavily on volunteer labor. We stated the population density of the area in which a ground ambulance organization is operating is expected to affect costs and revenues in a number of ways. Organizations serving rural and super-rural areas generally are likely to face lower demand for services, and thus, deliver a smaller number of transports. In addition, in rural and super-rural areas the average distance traveled per transport tends to be greater. We further stated that payment rates will also differentially impact revenue by population density because the Medicare AFS accounts for mileage and, in addition, rural and super-rural providers and suppliers receive higher temporary add-on payments.

- *Volume of transports.* If there are economies of scale, organizations providing a larger volume of services typically would face lower per-transport costs. We stated our analysis found the majority of ground ambulance organizations have a low volume of transports, but there are a small number of organizations with a very high volume of transports. Additionally we stated that suppliers providing a large volume of transports are more likely to be for-profit organizations.

⁹⁷ This report is available at <https://www.gao.gov/assets/650/649018.pdf>.

⁹⁸ This report is available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/Downloads/Report-To-Congress-September-2015.pdf>.

- *Ownership.* For-profit (non-government), non-profit (non-government), and government ground ambulance organizations have different business models and mixes of services, leading to different costs. We stated conceptually, for-profit organizations maximize profit and operate only in markets and service lines with positive margins and that non-profit and government ground ambulance organizations more broadly provide emergency service to communities and may be organized and operated in a way that does not maximize profits. The 2012 GAO report found ground ambulance organizations with more limited government support are more likely to have incentives to keep costs lower. They found that for each 2 percent decline in the average length of government subsidy there was a 2 percent decline in the average cost per transport. As a result, we stated we expect that costs will differ based on ownership.

- *Types of services provided.* One key distinction in the types of services provided is between emergency transports and non-emergency (for example, scheduled or inter-facility) transports. We stated that for-profit suppliers are more likely than others to specialize in non-emergency scheduled transports. We stated that another key distinction is between the level of service provided (for example BLS versus ALS).

- *Staffing.* The level of staff training (for example, EMTs versus paramedics) and the number of staff deployed is driven in part by the type and volume of calls, the availability and proximity of the nearest providers, and resources available in that community. We stated that some suppliers use static staffing models that use set staff schedules, whereas others use a dynamic, or flexible, staffing model that calls upon staff if there is a surge in demand.

- *Use of volunteer labor.* Volunteer labor tends to be more common among small, government-based ambulance suppliers operating in rural and super-rural settings.

- *Response times.* In many cases, response times are related to the population density of the area in which they operate, with rural areas having response times more than double those of urban areas. We stated that rural and super-rural ambulance providers and suppliers generally travel greater distances to get to patients and transport them to a hospital or the nearest appropriate facility. We also stated that variation in response times within urban areas might also occur, for example if there is significant emergency department crowding, or in extreme cases diversion that requires the ambulance to travel further to another hospital or wait with the patient until a bed is available and that this extra time affects the availability of the ambulance and the staff for subsequent trips, potentially increasing response times.

We stated we were not aware of any existing data source that lists all ground ambulance organizations or one that encompasses all the characteristics that impact costs and revenues described above. We stated that Medicare claims and enrollment data is the only source of data for which we were aware that has all the providers and suppliers that bill Medicare in a given year. We stated that several of the organizational characteristics we discuss above (including provider versus supplier status, ownership, service area population density, Medicare billed transport volume, and type of services provided) are available from Medicare data while others, such as the use of volunteer labor, staffing model, and response times are not.

We proposed to stratify the sample based on provider versus supplier status, ownership (for-profit, non-profit, and government), service area population density (transports originating in primarily urban, rural, and super rural zip codes), and Medicare billed transport volume categories. Based on our analysis of the number and distribution of ground ambulance organizations' transports in 2016, we proposed volume categories of 1 to 200, 201 to 800, 801 to 2500, and 2501 or more paid Medicare transports. The volume categories aim to divide ground

ambulance organizations into roughly similar-sized groups, while separating ground ambulance organizations with very high volume (that is, greater than 2500 Medicare transports per year) into a separate category. We stated we would expect that these highest-volume ground ambulance organizations may face different costs than lower-volume organizations due to economies of scale.

We proposed to focus on these four characteristics due to data availability, and our analyses that show these to be key defining characteristics of ground ambulance organizations (which are also described in the CAMH report). We stated that service area population density and Medicare billed transport volume have a direct impact on ground ambulance revenue, which is one of the categories of data that we are required to collect by section 1834(l)(17)(A) of the Act. We stated that through Medicare claims and enrollment data, we believe we have enough information to stratify ground ambulance organizations on these four characteristics. This stratification approach results in 36 groupings of ground ambulance suppliers (defined by combinations of the three ownership categories, three service area population density categories, and four Medicare billed transport volume categories) and the same number of groupings for ambulance providers.

In some of these groupings, there are only a handful of ground ambulance organizations providing ground ambulance services with a specific set of the four characteristics. We stated this could result in situations where few or no ground ambulance organizations with the specific set of characteristics were sampled. To minimize this risk and avoid situations where we are sampling from strata that contain only a few ambulance providers and suppliers in the entire population, we proposed to stratify ground ambulance providers, which account for only 6 percent of ground ambulance organizations combined, based on service area population density

only. We proposed to use this characteristic to stratify providers rather than another characteristic because section 1834(l)(17)(A) of the Act specifically requires the Secretary to develop a data collection system to collect information on ground ambulance services furnished in different geographic locations, including rural areas and low population density areas described in section 1834(l)(12) of the Act (super rural areas).

We also proposed to collapse the two highest Medicare ground ambulance transport volume categories (801-2500 and 2501 and more transports) into a single category (801 and more transports) for for-profit ground ambulance suppliers that primarily service super-rural areas due to the small number of ground ambulance organizations in these two volume categories. We stated the proposed sampling rate of 25 percent aims to meet a threshold that will provide an adequate degree of precision for estimates within each strata subgroup (that is, provider versus supplier status, ownership (for-profit, non-profit, and government), service area population density (transports originating in primarily urban, rural, and super rural zip codes), and Medicare billed transport volume categories). The specific threshold is 200 expected responses in each subgroup. This number of expected responses will ensure that small to medium differences in means between groups (that is, affect size) can be detected.

We stated that a 25 percent sampling rate is expected to result in more than 200 responses in each subgroup except for ground ambulance providers (where we expect 153 responses with a 25 percent sampling rate) and that a 25 percent sampling rate will result in more than 200 expected responses for other organizations not represented in the strata, including organizations providing primarily non-emergency transports and transports to and from dialysis facilities. We stated that we also expect that a 25 percent sampling rate will result in more than 200 responses for organizations that rely primarily on volunteer labor, as well as for those who do not.

We invited comments on all our proposals for sampling including our proposals on eligible organizations, methods for sampling, sampling at the NPI level, sampling of organizations using volunteer labor, sampling files, and sampling rates. We also invited comments on our proposals to collect data from ground ambulance organizations that bill Medicare, and the use of a stratified random sample.

We received comments on our proposals for sampling as described in this section. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally very supportive of our proposals and agreed that the data collection effort must cover ground ambulance organizations of all types (government, for-profit, not-for-profit, provider-based, and volunteer) regardless of size and service area (urban, rural and super rural). They stated that all ground ambulance organizations must be represented in the samples to allow for stakeholders and policy-makers to understand the true cost of providing ambulance services in the geographically diverse areas of the country. Some commenters also believe that this information is important to support the permanent inclusion of the urban, rural, and super-rural add-ons into the AFS payment. Commenters noted that while it may be more difficult for some smaller or rural/super-rural ground ambulance organizations to provide such data, their data are essential for policy-makers to evaluate the ambulance benefit in its entirety.

One commenter stated that, while they believe it is important for organizations that rely on volunteer labor to be included in the sampling, they encourage CMS to consider exempting from sampling ground ambulance organizations with very low volumes of Medicare-billed transports where the payment reduction for not reporting data would be less than the cost of reporting data. One commenter advocated for excluding organizations with workforces

consisting of 50 percent or more volunteer labor because of the administrative burden associated with reporting. Another commenter expressed concern that the penalties for not reporting would endanger the financial health for small, rural ambulance organizations.

Response: We recognize that there may be some ground ambulance organizations that have limited resources that affect their ability to report the required information, and that for these ground ambulance organizations, a 10 percent payment reduction in Medicare payments could result in significant financial hardship. However, we believe that it is critical that ground ambulance organizations of all types submit data so that we can all understand better the costs of furnishing ground ambulance services, including ground ambulance services furnished in very low-volume or in rural and super-rural areas. This is particularly important because several payment policies such as current add-on payments specifically apply to ground ambulance services in rural and super-rural areas, and therefore, we do not agree that small ground ambulance organizations should be excluded from sampling. While some very low volume ground ambulance organizations may conclude that the payment reduction will be less than the estimated costs of collecting and reporting data, we believe it is important to offer all ground ambulance organizations the opportunity to submit data and participate in this important national data collection activity. If we were to systematically exclude any category of ground ambulance organizations, for example organizations with very low volumes of Medicare-billed ground ambulance services, there would be gaps in our understanding of important segments of ground ambulance organizations and their role in the country's emergency response system. We note that section 1834(l)(17)(A)(D)(iii) of the Act authorizes the Secretary to exempt a ground ambulance provider or supplier from the 10 percent payment reduction for an applicable period in the event of significant hardship, such as bankruptcy, which is discussed in detail below in this

rule.

Comment: Many commenters stated that they support a stratified sampling approach and believe the proposed approach should allow the end users of the data to ensure a representative sample and facilitate analysis of subgroups of ground ambulance organizations, but would have preferred that CMS first obtain information about organization type, utilization patterns, and other relevant organizational characteristics to support a stratified random sample before collecting cost, revenue and other data. They believed CMS would have been better positioned to ensure that, when it fields the data collection instrument it is obtaining a representative sample of all types, sizes, and geographic distribution of ground ambulance services if they had first collected organizational data from all ground ambulance organizations. Commenters asked that CMS work closely with stakeholders during the first years of the system to identify and resolve any problems that arise. They also stated that prior research echoed the need for a stratified sample due to variation in the level of transport costs resulting from various business models present in the industry.

Response: As we have stated above, we do not believe that it is necessary to first collect only organizational characteristic data from all ground ambulance organizations prior to collecting cost, revenue and utilization data. We believe that CMS' claims and enrollment data are sufficient for the purposes of selecting stratified samples of ground ambulance organizations.

Comment: Many commenters stated that they agree that selecting 25 percent of ground ambulance services (defined at the National Provider Identifier level) is appropriate for each of the 4 years of the system. They quoted prior research that has indicated that a sample of approximately 15-25 percent of the ambulance industry should be sufficient to ensure cost data are representative of the industry overall and for subgroups of ground ambulance organizations,

reliable in establishing ambulance payment rates, and a significant improvement on the data used to establish the current payment rates. They also stated that prior efforts to sample ambulance cost data have generated varying results and in order to generate a representative sample CMS needs a larger sample than has been conducted in the past. They stated that business models of ambulance providers and suppliers vary in terms of their service areas, types of services, and most importantly their volume of transports. To account for this variation, the commenters recommended that the sample should support analysis for 14 different subgroups of ground ambulance organizations: super-rural (majority of transport pick-ups in super rural zip codes), rural (majority of transport pick-ups in rural zip codes), urban (majority of transport pick-ups in urban zip codes), for-profit, not-for-profit, government entity (not including fire/public safety), volunteer-based, hospital-based, fire/public safety-based, low transport volume (less than 600 transports per year), medium transport volume (600 to 5000 transports per year), high transport volume (more than 5000 transports per year, Advanced Life Support (ALS) transport-focused (greater the 90 percent of transports are ALS), and Basic Life Support (BLS) transport-focused (greater than 90 percent of transports are BLS). These commenters stated that it may be necessary to sample 100 to 200 of each type of providers and suppliers. They stated that they believe that response rates are not likely to be a problem in collecting the data due to the reduction Congress has tied to non-responders.

Response: Our proposal to sample 25 percent of all ground ambulance organizations in each of the 4 years is based on our analysis which shows that this approach will ensure we have enough data for analysis and that the sample is a representative of all ground ambulance organizations in each of the years of data collection. We believe that this approach is consistent with the statutory requirements regarding data collection. As we noted in the proposed rule, we

believe those analyzing the data will want to calculate estimates for subgroups of the ground ambulance organizations in the sample, for instance ground ambulance providers operating primarily in super-rural areas that are government owned or for profit ground ambulance providers operating in urban areas. We also noted that we believe that 200 responses per subgroup will be necessary in order to calculate estimates of sufficient precision within different subgroups of ambulance organizations. Furthermore, we noted that a sample of 25 percent of ground ambulance organizations will result in data collected from more than 200 ground ambulance organizations in nearly all of the subgroups that we noted may be of interest to those analyzing the data. Lastly, we said that response rates lower than 25 percent would result in fewer than 200 sampled ground ambulance in additional subgroups of ground ambulance organizations and that estimates from data summarized from fewer than 200 respondents in a particular type or category will be less precise than necessary to determine the adequacy of payments.

Comment: One commenter suggested that CMS select a sample of respondents that is in proportion of their volume of Medicare-billed ambulance services. For example, if 94 percent of Medicare ground ambulance claims are submitted by independent ambulance suppliers, then ideally 94 percent of each year's survey sample would consist of independent ambulance suppliers. Similarly, the 50 percent of organizations that make up only 3 percent of Medicare ground ambulance claims would make up only 3 percent of the sample. They also suggested that to allow MedPAC to produce the most accurate analysis for their Congressional report by the March 15, 2023, statutory deadline, MedPAC would need to receive data from a robust sample of ambulance organizations by March 2022. Therefore, they believe the first year's survey sample should be large enough to produce statistically reliable results using that year's data

alone. In addition, they stated that all high-volume ambulance organizations (for example, the 10 percent of organizations that provide 70 percent of Medicare ground transports) should be surveyed within the first 2 years of data collection with 50 percent of these organizations surveyed in the first year and the other 50 percent surveyed in the second year.

Response: We do not agree that ground ambulance organizations should be sampled solely in proportion to their volume of Medicare ground ambulance service claims. While such an approach would collect information sooner from the small number of ground ambulance organizations that account for the majority of Medicare ground ambulance transports, it would shift the focus of the data collection effort almost entirely towards these large organizations at the expense of including smaller organizations. Our analysis indicates that the top 3 percent of organizations in terms of Medicare ground ambulance transport volume (all with more than 10,000 transports per year) account for 39 percent of total Medicare transports while the bottom 42 percent (all with fewer than 200 transports per year) account for only 2 percent of total Medicare transports. We believe that under our approach, each ground ambulance organization has an equal probability of being included in the sample. We also agree with other commenters that stressed the importance of a broad and inclusive approach to collecting data from all types of ground ambulance organizations, and sampling solely in proportion to volume would dramatically decrease the contributions of some types of ground ambulance organizations to the data collection effort.

We believe that the 25 percent sample proposed and supported by almost all commenters will yield sufficient data for analysis of the data after each year of data collection. While sampling at higher rates for some or all types of ground ambulance organizations in earlier years would result in additional data in the first year, we do not believe that the additional data is

necessary to conduct an accurate analysis of the data. We disagree with the recommendation to sample ground ambulance organizations with the highest Medicare volume at higher rates in the initial years of data collection due to the concerns previously discussed about sampling solely in proportion to volume. We are also concerned that sampling larger ground ambulance organizations more heavily in the first 2 years of data collection will deter smaller ground ambulance from reporting because they will perceive that their data will not be used in the analysis.

After consideration of the comments, we are finalizing our sampling proposals to implement a 25 percent stratified sample in each of the first 4 years of data collection. We are also finalizing our proposal to codify the representative sample requirements at § 414.626(c).

6. Collecting and Reporting of Information under the Data Collection System

For each data collection year, section 1834(l)(17)(C) of the Act requires ground ambulance organizations identified as part of the representative sample to submit information specified under the system, with respect to a period for the year (referred to as the “data collection period”), in a form and manner and at a time (referred to as the “data reporting period”) specified by the Secretary. In this section, we proposed to define the data collection period and the data reporting period. In determining when the data collection and reporting periods should fall, our objectives were to: (1) allow selected ground ambulance organizations sufficient time to collect and report the required information; and (2) collect the data for analysis in the least burdensome manner.

We considered annual (that is, 12-month) data collection periods and shorter data collection periods (for example, a 6-month period). We proposed a 12-month data collection

period because a shorter period could result in biased data due to seasonality in costs, revenue, or utilization among ground ambulance organizations.

As we stated previously, ambulance providers and suppliers constitute a diverse group of organizations with varied annual accounting practices. Accordingly, we proposed to define the data collection period as a continuous 12-month period of time, which is either the calendar year aligning with the data collection year, or when an organization uses another fiscal year for accounting purposes and the organization elects to collect and report data over this period rather than the calendar year, the 12-month period that is their fiscal year that begins during the data collection year. We proposed this data collection period based on feedback from ground ambulance organizations that stated that they prefer to collect data based on an annual accounting period (either calendar year or fiscal year) already used by the organization, and that requiring all organizations to report on the same 12-month period (for example, calendar year) could involve significant additional burden in terms of data collection and reporting. We believe that providing flexibility in collecting information under the data collection system would reduce the burden on ground ambulance organizations.

Therefore, we proposed that the first data collection period be January 1, 2020 through December 31, 2021, with organizations reporting on a calendar year basis collecting data from January 1, 2020 through December 31, 2021, and organizations reporting on a fiscal year basis collecting data over a continuous 12-month period of time from the start of the fiscal year beginning in calendar year 2020. Upon being notified that they are selected as part of the sample, ground ambulance organizations must notify CMS of their annual accounting period within 30 days according to the instructions in the notification letter, so that CMS is aware of when their data collection and data reporting periods would begin. We proposed that respondents would

additionally confirm the data collection period when reporting data via the data collection instrument (section 2, question 5).

We also proposed that ground ambulance organizations would have up to 5 months to report to CMS (data reporting period) the data following the end of its 12-month data collection period. For example, if a ground ambulance organization is selected as part of the representative sample for the CY 2020 data collection year, and notifies CMS that its annual accounting period is based on a calendar year, the data collection period for this ground ambulance organization would begin on January 1, 2020 and end on December 31, 2020, and the data reporting period would be January 1, 2021 through May 31, 2021. A ground ambulance organization selected for CY 2020 that notifies CMS that its annual accounting period is based on a fiscal year basis with a fiscal year beginning on June 1, 2020 would have a data collection period from June 1, 2020 through May 31, 2021 and a data reporting period from June 1, 2021 through October 1, 2021. Since a 5-month reporting period is enough time for entities that file cost reports with Medicare to complete and submit their data, we believe it should also provide adequate time for ground ambulance organizations to report information under the data collection system to CMS. This will allow providers and suppliers time to validate the information and certify the accuracy of their data required under the data collection before reporting it to CMS.

We proposed to codify the data collection and reporting requirements for selected ground organizations at § 414.626(b).

Tables 38 and 39 illustrate various examples of data collection periods and the data reporting periods that were proposed. Please note that an individual ground ambulance organization would only be selected to participate in one data collection and reporting period,

and that the specific data collection and reporting period dates might vary for each organization and be different than the dates noted in Tables 38 and 39.

TABLE 38: Example of a Data Collection and Reporting Period for a Ground Ambulance Organization with a Calendar Year Accounting Period

Year	Data Collection Period	Data Reporting Period
1	01/01/2020—12/31/2020	01/01/2021—05/31/2021
2	01/01/2021—12/31/2021	01/01/2022—05/31/2022
3	01/01/2022—12/31/2022	01/01/2023—05/31/2023
4	01/01/2023—12/31/2023	01/01/2024—05/31/2024

TABLE 39: Example of a Data Collection and Reporting Period for a Ground Ambulance Organization with an Accounting Period Not Based on a Calendar Year

Year	Data Collection Period	Data Reporting Period
1	06/01/2020—05/31/2021	06/01/2021—10/31/2021
2	06/01/2021—05/31/2022	06/01/2022—10/31/2022
3	06/01/2022—05/31/2023	06/01/2023—10/31/2023
4	06/01/2023—05/31/2024	06/01/2024—10/31/2024

We invited comments on our proposal to use a 12-month data collection period. We also invited comments on our proposal to give sampled ground ambulances the flexibility to collect data on either a calendar year basis or on the basis of the ground ambulance organization’s fiscal year. In addition, we invited comments on our proposal to allow a ground ambulance organization 5 months to report the data collected during data collection period to CMS through the data collection system. We stated that any ongoing collection of data after the initial 4-year period would be addressed in future rulemaking.

The following is a summary of the comments we received and our responses.

Comment: One commenter requested that we issue a technical correction to the proposed rule to correct the year for the first data collection period and the reporting calendar year.

Response: We thank the commenter for bringing this error to our attention and note that we inadvertently stated in one place in the proposed rule that the first data collection period

would be January 1, 2020 through December 31, 2021 (84 FR 40699). We note that we correctly stated the dates of the first data collection period throughout the remainder of the proposed rule and confirm again here that the correct dates of the first data collection period are January 1, 2020 through December 31, 2020.

Comment: All commenters supported our proposal to allow ground ambulance organizations to report based on either a calendar year or their organization's fiscal year. We received no comments on the data collection period, and no comments on the proposal to allow a ground ambulance organization 5 months to report the data collected during data collection period.

Response: We appreciate the commenters' support of these proposals.

Comment: One commenter noted that internal systems of ground ambulance providers and suppliers will have to be changed during 2020 and that parameters will need to be edited in order to obtain quality data in a reasonable time.

Response: While we understand that system changes may be necessary for some ground ambulance organizations who are sampled in the first data collection period, we believe that most ground ambulance organizations will be able to complete the data collection requirements within the specified timeframe.

After consideration of the comments, we are finalizing the data collection period as a continuous 12-month period of time, which is either the calendar year aligning with the data collection year, or the organization's 12-month fiscal year that begins during the data collection year when an organization uses fiscal year for accounting purposes and elects to collect and report data over this period rather than the calendar year. We are also finalizing our proposal to allow a ground ambulance organization 5 months to report the data collected during data

collection period. We are also finalizing our proposals to codify the data collection and reporting requirements for selected ground ambulance organizations at § 414.626(b).

7. Payment Reduction for Failure to Report

a. General Information and Applicable Period

Section 1834(l)(17)(D)(i) of the Act requires that beginning January 1, 2022, subject to clause (ii), the Secretary reduce the payments made to a ground ambulance organization under section 1834(l)(17) of the Act for the applicable period by 10 percent if the ground ambulance organization is required to submit data under the data collection system with respect to a data collection period and does not sufficiently submit such data. Section 1834(l)(17)(D)(ii) of the Act defines the applicable period as a year specified by the Secretary not more than 2 years after the end of the period for which the Secretary has made a determination that the ground ambulance provider or supplier failed to sufficiently submit information under the data collection system.

As previously discussed, we proposed to define the data collection and data reporting periods based on the ground ambulance organization's annual accounting period (either calendar year or fiscal year). The timeline for the determination of the 10 percent reduction to payments would depend on: (1) the 12-month data collection period based on the organization's accounting period; (2) the end of the data reporting period that corresponds with the selected data collection period; and (3) the time it would take CMS to review the data to determine whether it had been sufficiently submitted. We proposed that we would make a determination that the ground ambulance organization is subject to the 10 percent payment reduction no later than the date that is 3 months following the date that the ambulance organization's data reporting period

ends. This timeframe will allow CMS to assess whether the required data was sufficiently submitted.

For example, if a ground ambulance organization is selected in the first sampling year and it reports to CMS that its annual accounting period is an October 1 through September 30th fiscal year, then its data collection period would be October 1, 2020 through September 30, 2021, and the data reporting period that would apply to the ground ambulance organization would be from October 1, 2021 - February 28 (or 29, if a leap year), 2022. We would make a determination regarding the sufficiency of that ground ambulance organization's reporting no later than June 1, 2022. With this timeframe, we would propose to apply the 10 percent reduction in payments, if applicable, for ambulance services provided by that ground ambulance organization between January 1, 2023 and December 31, 2023, because under section 1834(l)(17)(D)(iii) of the Act, the applicable period must be one year in length. As another example, if a ground ambulance organization's annual accounting period is the calendar year, its data collection period would be January 1, 2020 through December 31, 2020, the data reporting period that would apply to the ground ambulance organization would be from January 1, 2021 - May 31, 2021, and we would make a determination regarding the sufficiency of that ambulance organization's reporting no later than August 31, 2021. With this timeframe, we would propose to apply the 10 percent reduction in payments, if applicable, for ambulance services provided between January 1, 2022 and December 31, 2022. The payment reduction would always be applied to ground ambulance transports provided during the calendar year that begins following the date that we determine that the ground ambulance organization is subject to the payment reduction.

We proposed that if we find the data reported is not sufficient, we would notify the ground ambulance organization that it will be subject to the 10 percent payment reduction for ambulance services provided during the next calendar year. We would interpret “sufficient” to mean that the data reported by the ground ambulance organization is accurate and includes all required data requested on the data collection instrument.

We proposed to apply the 10 percent payment reduction for the appropriate calendar year as described above to ambulance fee schedule payments as described in § 414.610. The payment reduction will apply to claims for dates of service during the applicable calendar year and will be applied to the final ambulance fee schedule payment, after all other adjustments have been applied under § 414.610(c). We proposed to codify the payment reduction by adding a new paragraph (c)(9) in § 414.610.

b. Hardship Exemption

Section 1834(l)(17)(A)(D)(iii) of the Act authorizes the Secretary to exempt a ground ambulance provider or supplier from the 10 percent payment reduction for an applicable period in the event of significant hardship, such as a natural disaster, bankruptcy, or other similar situation that the Secretary determines interfered with the ability of the ground ambulance provider or supplier to submit such information in a timely manner for the specified period.

We recognize that there may be some ground ambulance organizations that have limited resources that affect their ability to report the required information, and that for these ground ambulance organizations, a 10 percent payment reduction in Medicare payments could result in significant financial hardship.

An example of this situation could be a ground ambulance organization that is located in a super rural area with such limited resources that it cannot report the required information without significantly increasing the possibility that it would need to file for bankruptcy.

Another example could be a ground ambulance organization that is located in an area that had recently experienced a natural disaster such as widespread flooding that caused the closure of a local emergency room or other facilities. Due to the increased demand for services and rerouting of patients, this ground ambulance organization might be unable to collect and report information in a timely manner.

We proposed that ground ambulance organizations that have experienced these or other similar situations could request a hardship exemption, and we would consider granting an exemption if the ground ambulance organization could demonstrate that the significant hardship interfered with its ability to submit the required data under the data collection system.

To request a hardship exemption, we proposed that a ground ambulance organization submit to CMS a completed request form, which can be found on the Ambulance Services Center Website (<https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html>), and that the following information be included:

- Ambulance Provider or Supplier Name;
- NPI Number;
- Ambulance Provider or Supplier Location Address;
- CEO and any other designated personnel contact information, including name, e-mail address, telephone number and mailing address (must include a physical address, a post office box address is not acceptable);
- Reason for requesting a hardship exemption;

- Evidence of the impact of the hardship exemption (such as photographs, newspaper, other media articles, financial data, bankruptcy filing, etc.); and
- Date when the ground ambulance organization would be able to begin submitting information under the data collection system.

We proposed that the completed hardship exemption request form be signed and dated by the Chief Executive Officer (CEO) or designee of the ambulance company, and be submitted as soon as possible, and not later than 90 calendar days after the date that the ground ambulance organization was notified that it will be subject to the 10 percent payment reduction as a result of not sufficiently submitting information under the data collection system. We proposed that the request form be submitted to the Ambulance ODF mailbox at AMBULANCEODF@cms.hhs.gov. Following receipt of the request form, we proposed to provide: (1) a written acknowledgement that the request has been received; and (2) a written response to the CEO and any designated personnel using the contact information provided in the request within 30 days of the date that we received the request. We also proposed to codify the hardship exemption requirement at § 414.626(d).

c. Informal Review

Section 1834(l)(17)(D)(iv) of the Act requires the Secretary to establish a process under which a sampled ground organization may seek an informal review of a determination that it is subject to the 10 percent reduction. To request an informal review, we proposed that a ground ambulance organization must submit the following information:

- Ground Ambulance Organization Name;
- NPI Number;

- CEO and any other designated personnel contact information, including name, e-mail address, telephone number and mailing address (must include a physical address, a post office box address is not acceptable);
- Ground ambulance organization's selected data collection period and data reporting period; and
- A statement of the reasons why the ground ambulance organization does not agree with CMS' determination and any supporting documentation.

We proposed that the informal review request must be signed by the CEO/designee of the ground ambulance organization and be submitted within 90 calendar days of the date that the ground ambulance organization received notice regarding the 10 percent reduction in payments. We proposed 90 calendar days to submit an informal review request to allow time for the ground ambulance organization to gather the information needed to support the request for informal review. We proposed that the request be submitted to the Ambulance ODF mailbox at AMBULANCEODF@cms.hhs.gov. Following receipt of the request for informal review, we will provide: (1) a written acknowledgement using the contact information provided in the request, to the CEO and any additional designated personnel, notifying them that the ambulance provider or supplier's request has been received; and (2) a written response to the CEO and any designated personnel using the contact information provided in the request within 30 days. We solicited comments on our informal review process. We also proposed to codify the informal review process in § 414.626(e).

We invited comments regarding all the proposals on the payment reduction for failure to report, including the applicable period, hardship exemption, and informal review.

We received comments on the proposals for the hardship exemption and informal review, and no comments on the applicable period. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposals regarding the hardship exemption and informal review. One commenter noted that the majority of patients in rural/super rural areas are Medicare beneficiaries and that in these areas, the ground ambulance organization may have a small call volume. The commenter stated that the ground ambulance organization may not understand how to complete the survey, and the financial impact of the 10 percent reduction would impact the ground ambulance organization's ability to stay in business. One commenter requested clarification on the length and timing of the 10 percent reduction for failure to report.

Response: We appreciate the support of the commenters. We will provide education and outreach to ground ambulance organizations that are selected to participate in the ground ambulance data collection system and will work directly with the affected organizations to the extent possible. As previously noted, the payment reduction would always be applied to ground ambulance transports provided during the calendar year for a one year period that begins following the date that we determine that the ground ambulance organization is subject to the payment reduction.

Comment: Some commenters supported the proposed process for applying for a hardship exemption. One commenter stated that the form and timeline seem appropriate and sufficient to allow ambulance organizations to seek the exemption. One commenter asked that CMS provide automatic hardship exemptions when a deadline falls during the period of natural disaster, such as a hurricane.

Response: We appreciate the support of the commenters on the proposed process for hardship exemption. While we understand that a natural disaster may affect the ground ambulance organization's ability to collect or submit the required data, we are unable to provide an automatic hardship exemption. Unless the ground ambulance organization applies for the exemption, we would have no way of knowing which ground ambulance organizations are affected or to what extent the disaster has affected them. All ground ambulance organizations that are selected to participate in the data collection system have up to 5 months to report the data collected during the data collection period, and we encourage them not to wait for the deadline to report. We understand it may be difficult to meet a deadline during a natural disaster and we will work with the affected ground ambulance organization to the extent possible.

Comment: A commenter requested clarification regarding when the hardship exemption form will be available and when the organization can apply for the exemption. Another commenter requested information on how the hardship exemption request will be evaluated.

Response: The hardship exemption request form will be available on our website when this final rule is published. A ground ambulance organization that has been selected to report cost, revenue, utilization, and other information under the ground ambulance data collection system may apply for a hardship exemption during their data collection period if they have experienced a hardship that prevents them from submitting the required information. Again, we remind organizations that they have 5 months to report their data and should try to submit it as soon as possible to avoid this type of situation. All hardship exemption requests will be evaluated based on the information submitted that clearly shows that they are unable to submit the required data due to a significant hardship, such as a natural disaster, bankruptcy, or other similar situation.

Comment: Some commenters supported the informal review process that we proposed to adopt and asked that we permit ground ambulance organizations to address any problems with their submitted data originally during a defined time period and without having to incur a payment reduction. The commenters stated that this correction would be prudent because of the lack of testing of the data collection instrument.

Response: We will work with the affected organization to the extent possible to correct any mistakes or omissions in the data they submitted in order to avoid incurring a payment reduction.

After consideration of the comments, we are finalizing all of our proposals regarding on the payment reduction for failure to report, including the applicable period, hardship exemption, and informal review. We are also finalizing our proposal to codify the payment reduction by adding a new paragraph (c)(9) in § 414.610, our proposal to codify the hardship exemption requirement at § 414.626(d) and our proposal to codify the informal review process at § 414.626(e). In the proposed rule, we inadvertently stated that the informal review process would be codified at § 414.610(e) (84 FR 40701).

Hardship exemption and informal review requests should be submitted to the Ambulance ODF mailbox at: AMBULANCEODF@cms.hhs.gov. Questions on the ground ambulance data collection system should be sent to AmbulanceDataCollection@cms.hhs.gov.

8. Public Availability

Section 1834(l)(17)(G) of the Act requires that the results of the data collection be posted on the CMS website, as determined appropriate by the Secretary. We proposed to post on our website a report that includes summary statistics, respondent characteristics, and other relevant results in the aggregate so that individual ground ambulance organizations are not identifiable.

We also proposed that the data above will be made available to the public through posting on our website at least every 2 years. The 2-year timeframe would allow CMS time to analyze the data that is being reported, factoring in the various accounting periods of the first group of sampled ground ambulance organizations (which have early accounting periods in the CY 2020 data collection year).

We proposed to post summary results by the last quarter of 2022, because we believe we may have most or all of the data requested by then. We invited comments on our proposals regarding the type of information that should be posted from the data collected and the timeline in which the results of the data collection should be posted on our website.

We invited comments regarding our proposals for public availability of the data.

We received comments on our proposals regarding the type of information that should be posted from the data collected, the timeline in which the results of the data collection should be posted on our website, and the public availability of the data.

The following is a summary of the comments we received and our responses.

Comment: One commenter stated that the report should be more detailed than the proposed summary statistics, respondent characteristics, and other relevant results in the aggregate. One commenter recommended that the data collected through the data collection system be made publicly available in various formats such as Public Use Files (PUF) accessible through the web, or other formats that will facilitate the use of the data for other purposes.

One commenter stated it is important that stakeholders have access to the data collection in a manner that is similar to the publicly available data obtained through traditional Medicare cost reporting. Some commenters encouraged CMS to incorporate the ambulance cost data into

the standard Healthcare Cost Report Information System (HCRIS) as an additional subsystem to the ground ambulance data collection system.

One commenter recommended that CMS follow the standard HCRIS file format and schedule for releasing ambulance cost data, including releasing two types of data files. This commenter recommended that the ambulance cost report PUF contain a subset of the data variables reported by ambulance suppliers and providers and may enable users to calculate provider margins and assess ambulance transport volume. The commenter requested data be available in multiple formats and also stated that CMS should follow the standard file formats as it releases these files to reduce the burden on researchers. The commenter also recommended that all ambulance cost report variables be defined with Medicare's Provider Reimbursement Manual. Lastly, the commenter stated that the individual ground ambulance organizations should not be identifiable in the results of the data collection on our website.

Response: We thank the commenters for their recommendations regarding the posting of the results of the data collection on the CMS website. We are exploring several mechanisms for posting of the report to our website. As such, we will consider the use of HCRIS and other PUFs to make the data publicly available. We intend to post as much data as possible, including summary statistics describing the data reported by subgroups of respondents, while protecting the confidentiality of the respondents.

Comment: One commenter stated that the information should be published more frequently than once every 2 years.

Response: We believe that the 2-year timeframe would allow us time to analyze the reported data, factoring in the various accounting periods. We will make the data available more frequently if possible.

Comment: Several commenters supported our proposal to make the data collected through the data collection system publicly available. One commenter stated that the data collected through the data collection system will be exceptionally valuable for agencies, payors, policy makers and other stakeholders and they recommend that the data be publicly available. One commenter stated that it is important that stakeholders have access to the data to be able to evaluate the adequacy of the payment system, not just MedPAC or other policymakers.

One commenter preferred that these data be shared publicly to provide more transparency in ambulance service rates. One commenter stated that given that this is the early stages of the development of the ambulance data collection system and the lack of testing, CMS might consider restricting access to the data in the first few years to only key stakeholders. This commenter stated that key stakeholders may be able to assist the agency with validating the initial data submitted by ambulance suppliers and providers.

Response: We appreciate the support of the commenters on our public availability proposals. We agree that making the data publically available is the most transparent approach and we anticipate that the data we make publicly available will be meaningful to all interested persons or organizations.

We did not receive any comments regarding our proposal to post summary results by the last quarter of 2022. After consideration of the comments, we are finalizing our proposals for public availability of the data including to post on our website a report that includes summary statistics, respondent characteristics, and other relevant results in the aggregate so that individual ground ambulance organizations are not identifiable. The data above will be made available to the public through posting on our website at least every 2 years and we will post summary results by the last quarter of 2022.

9. Limitations on Review

Section 1834(l)(17)(J) of the Act provides that there shall be no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the data collection system or identification of respondents. We proposed to codify the limitations on review at § 414.626(g). We did not receive any comments on this proposal and are finalizing it as proposed.

outcome is highly uncertain because the available information on which to base estimates is limited and is not directly applicable to a new Medicare payment. The cost and utilization estimates are based on Medicare and Medicaid claims data for beneficiaries with OUD, together with statistics about the types of services typically furnished at OTPs.

It is difficult for us to predict how coverage of OTP services will specifically affect the market. We anticipate current OTPs may expand access to care for Medicare beneficiaries since they will be able to receive payment from Medicare for services furnished to beneficiaries when they previously were unable to do so. Coverage may also create financial incentives to establish new OTPs. However, since TRICARE, Medicaid, and some private payers already pay for OTP services, it is less clear whether the presence of Medicare payment rates will have any effect on current rates for OTP services or on new rates should additional private coverage be established.

2. Changes to the Ambulance Physician Certification Statement Requirement

This final rule will clarify the requirements at §§ 410.40 and 410.41 regarding the requirements for physician certification and non-physician certification statements and expand the list of staff members who can sign non-physician certification statements. While we believe that clarification of the regulatory provisions associated with physician certification and non-physician certification statements is needed and would be well received by stakeholders, we do not believe that these clarifications would have any substantive monetary or impact the amount of time needed to complete the certification statements. We believe the primary benefit of the clarification would be for providers and suppliers in preparing and submitting the original certification statements. It is feasible the clarification could result in fewer claims being denied. However, hypothetically, these denials are likely a small subset of the ambulance claim denials and those denied for technical PCS issues are likely appealed and overturned.

Moreover, we have examined the impact of expanding the list of individuals who may sign the non-physician certification statement. This added flexibility in accessing additional individuals to sign a non-physician certification statement would be needed only when the physician was unavailable. Thus, while we anticipate that some providers would use the increased flexibility, the precise impact is not calculable.

3. Medicare Ground Ambulance Data Collection System

As discussed in section III.B.2. of this final rule, section 50203(b) of the BBA of 2018 added a new paragraph (17) to section 1834(l) of the Act, which requires the Secretary to develop a data collection system to collect cost, revenue, utilization, and other information determined appropriate with respect to providers and suppliers of ground ambulance services. In section III.B.4 through III.B.7. of this final rule, we outline the provisions that implement this section, including the data that will be collected through the data collection system, sampling methodology, requirements for reporting data, payment reductions that will apply to ground ambulance providers and suppliers that fail to sufficiently report data and that do not qualify for a hardship exemption, informal review process that will be available to ground ambulance providers and suppliers that are subject to a payment reduction, and our policies for making the data available to the public.

We estimate that ground ambulance providers and suppliers will need to engage in two primary activities with respect to these requirements, both of which will require them to incur cost and burden: data collection and data reporting. The data collection activity includes: (1) reviewing instructions to understand the data required for reporting; (2) accessing existing data systems and reports to obtain the required information; (3) obtaining required information from other entities where appropriate; and (4) if necessary, developing processes and systems to

collect data that are not currently collected, but that they will be required to report under the data collection system. The data reporting activity includes entering the collected information in the Medicare Ground Ambulance Data Collection Instrument.

To estimate the data collection impact, we assumed that each ground ambulance organization that is selected to submit data for a year would take up to 20 hours to collect the required data, which would include 4 hours to review the instructions and 16 hours to collect the required data. These estimates were informed by our discussions with ambulance organizations during stakeholder engagements and through more in-depth interviews with nine ambulance organizations for the purpose of soliciting feedback on data collection instrument items as described in section III.B.3. and III.B.4. of this final rule. Most participants indicated that they would be able to provide some of the required information with an investment of 1-2 hours and complete information with additional hours to collect the missing data. Many participants indicated that they would need to reach out to other staff at the organization, at contracted organizations (such as billing companies), or at other entities (such as municipal government financial staff for government ambulance organizations) to collect required information that was not in the organization's accounting or billing systems. Some participants indicated that their organization would need to adjust data collection processes or collect new data over the course of a year to ensure that required data was available in the appropriate format prior to submission.

Actual data collection and reporting will vary depending on the mix of employees at sampled ambulance organizations, the staff with available time to dedicate to data collection and data reporting activities at each organization, the staff in different roles that already perform similar activities in each organization, and whether billing services are contracted out or conducted internally.

Because we expect that the staff (by category) that will contribute to data collection and reporting will be highly variable across ground ambulance organizations, we calculated a blended mean wage for the purposes of estimating burden. Table 121 lists the Standard Occupational Classification (SOC) categories contributing to the blended wage, the mean wage for each SOC specific to North American Industry Classification System (NAICS) industry code 621910 (Ambulance Services), and the relative contribution of each SOC to the blended mean. The source mean wage and employment data is from the Bureau of Labor Statistics May 2018 Occupational Employment Statistics data (available from <https://download.bls.gov/pub/time.series/oe/>) for the indicated SOC and NAICS codes, which was most recently available wage and employment data set. We assumed that financial clerks (SOC category 433000) would account for 25 percent of the total data collection and reporting effort, and that six other SOC categories would contribute to the remaining 75 percent (see Table 121).

TABLE 121: Estimated Mean Hourly Wages for Occupations Involved in Data Collection

Standard Occupational Classification Category	Mean Hourly Wage (\$)	Weight (% Effort)*
Top Executives (111000)	51.49	17%
Other Management Occupations (119000)	39.23	12%
Business and Financial Operations Occupations (130000)	28.60	15%
Secretaries and Administrative Assistants (436010)	18.11	10%
Other Office and Administrative Support Workers (439000)	16.20	10%
Financial Clerks (433000)	18.51	25%
First-Line Supervisors of Office and Administrative Support Workers (431011)	27.92	10%
Blended Mean Hourly Wage	28.91	100%

*Note: Weights may not sum to 100 percent due to rounding. Source: Bureau of Labor Statistics Occupational Employment Statistics, May 2018, available from <https://download.bls.gov/pub/time.series/oe/>.

In addition, we calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage. Although we recognize that fringe benefits and overhead costs may vary significantly by employer, and that there are different accepted methods for estimating these

costs, doubling the mean blended wage rate to estimate total cost is an accepted method to provide a reasonably accurate estimate. Therefore, assuming a mean blended wage of \$28.91 for data collection, and assuming the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, we calculated a wage plus benefits estimate of \$57.82 per hour of data collection. To calculate the total data collection cost per sampled ground ambulance organization, we multiplied the time required for data collection by the burdened hourly wage (20 hours * \$57.82/hour) for a total of \$1,156.

We discussed several sampling options in section III.B.5. of this final rule. We finalized our proposed sampling rate of 25 percent that would yield an expected 2,690 respondents (based on 2016 data) in the first sample, resulting in a total estimated data collection cost of \$3,110,684 (2,690 respondents * \$1,156 per respondent).

To estimate the cost of data reporting, we assumed it will require 3 hours to enter, review, and submit information into the proposed web-based data collection system. The estimate of 3 hours was also informed by interviews with nine ambulance organizations to solicit feedback on the data instrument items under consideration. We included time for staff to review the collected data before entering it into the data collection system. We also assumed that staff responsible for reporting the data would have the same blended hourly wage used to estimate data collection costs above (\$28.91) as the staff that collected the data. Again, assuming the cost of overhead at 100 percent of the mean hourly wage, we calculated a wage plus benefits estimate of \$57.82. Therefore, we estimate a per-respondent cost for data submission of \$173.46 (3 hours * \$57.82/hour). To calculate the total cost for data reporting under a 25 percent sampling rate, we multiplied the number of ground ambulance organizations sampled annually by the time required

for data entry times the total hourly wage estimate, for a total of \$466,603 across all respondents (2,690 respondents * 3 hours * \$57.82/hour).

Adding the total data collection and reporting costs yields a total annual impact for ground ambulance organizations of \$3,577,287 (\$3,110,684 for data collection [2,690 respondents * 20 hours * \$57.82/hour] + \$466,603 total cost for data submission [2,690 respondents * 3 hours * \$57.82/hour]) with a 25 percent sampling rate. Our estimate of total annual impact would be lower at \$1,430,649 (\$1,244,042 for data collection [1,076 respondents * 20 hours * \$57.82/hour] + \$186,606 for data submission [1,076 respondents * 3 hours * \$57.82/hour]) under a 10 percent sampling rate alternative and higher at \$7,153,244 (\$6,220,212 for data collection [5,379 respondents * 20 hours * \$57.82/hour] + \$933,032 for data submission [5,379 respondents * 3 hours * \$57.82/hour]) under a 50 percent sampling rate. In all cases, the estimated cost of collecting and reporting data is \$1,330 per organization sampled (\$1,156 for data collection [20 hours * \$57.82/hour] + \$173.46 for data submission [3 hours * \$57.82/hour]). The per-organization estimate reflects an average. Based on discussions with ambulance organizations to provide feedback on instrument items, we do not anticipate that larger or smaller ambulance organizations in terms of transport volume, costs, or revenue will face systematically more or less burden in data collection or reporting. While larger organizations generally have higher transport volumes, costs, and revenue, and more complex financial arrangements that may increase reporting burden, they also tend to have existing data collection and reporting processes and staff that will reduce the additional effort required to submit the required data. On the other hand, while smaller organizations have less data to collect and report, they may not have current processes in place to begin collecting some required data.

Comment: Two commenters disagreed with our estimate to complete the survey. One commenter stated for smaller organizations, compliance with the proposed cost reporting requirements will take considerably longer than the 20 hours over the course of 12 months estimated by CMS because a lot of the data being sought is not currently collected or sorted. The other commenter stated that the proposed estimate of 20 hours is not valid and should be 40 hours but would not include the time taken by others, such as the dispatcher or medical director, to collect the data. According to the commenter, the volunteer services do not collect a lot of data that is not directly needed for their operations and thus much of this will be new data.

Response: We understand that the length of time it will take to complete the data collection will vary considerably, depending on numerous factors including the organizational structure of the ambulance organization, the existing accounting and cost reporting system, and the size and characteristics of the ambulance organization. For some, the amount of time required will be less than the estimate, and for others, it will be more. The estimate we provided is based on our experience in working with ambulance organizations during the development of the survey, and the time generally required by other programs with similar data collection requirements. We note that the data collection system was designed so that respondents only are required to answer the questions that are relevant for their organization, so for some organizations, the reporting requirements will also be less than for others.

b. Hardship Exemption Process

As discussed in section III.B.7.b. of this final rule, we proposed a process for ground ambulance organizations to request and for CMS to grant hardship exemptions from the 10 percent payment reduction. To request a hardship exemption, we proposed that a ground ambulance organization would be required to complete and submit a request form that we would

make available on the Ambulances Services Center website at

<https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html>.

We estimate that 25 percent of the total number of ground ambulance organizations will be selected each year as the representative sample to report the required information under the data collection system. That is, 25 percent out of the total 10,758 NPIs, or 2,690 ambulance providers and suppliers.

While we expect that few, if any, ground ambulance organizations will request a hardship exception, we do not have experience in collecting data from ground ambulance organizations that could be used to develop an estimate, so we based our estimate on the total number of organizations being surveyed. As a result, we estimated that a total of 2,690 ground ambulance organizations would apply for a hardship exemption, and that it would take 15 minutes for each of these ground ambulance organizations 15 minutes to complete and submit the request form.

We assumed for purposes of this estimate that the mix of staff responsible for completing this form would have the same blended hourly wage used to estimate the data collection and data reporting costs. We also calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, as we did above. As a result, we estimated that the total cost burden associated with the completion and submission of the hardship exemption request form would be approximately \$38,884.

We did not receive any comments on our estimate to complete the hardship exemption form. As we discussed in section III.B.7.b. of this final rule, we are finalizing our proposed process for hardship exemptions.

c. Informal Review Process

As discussed in section III.B.7.c. of this final rule, we proposed a process for a ground ambulance organization to seek an informal review of our determination that it is subject to the 10 percent reduction.

We estimate that a collection of information burden of 15 minutes for a ground ambulance organization that is requesting an informal review to gather the requested information and send an e-mail to our AMBULANCEODF mailbox.

We used the total number of ambulance organizations that will be surveyed each year to develop our estimates and estimated a total burden of 40,350 minutes (15 x 2,690) or 672.5 hours for 2,690 ground ambulance organizations to complete this process. Taking into account the same blended mean hourly wage and fringe benefits as we did for our other estimates, we estimated that the total for all sampled ground ambulance organizations to gather the requested information and submit the form would be approximately \$38,884.

We did not receive any comments on our estimate to collect and submit the information for an informal review. As we discussed in section III.B.7.c. of this final rule, we are finalizing our proposed process to request an informal review.

4. Intensive Cardiac Rehabilitation (ICR)

As discussed in section III.C. of this final rule, we are adding stable, chronic heart failure (CHF) (defined as patient with left ventricular ejection fraction of 35 percent or less and NYHA class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks) to the list of covered conditions for ICR, as well as, the ability for use to use the NCD process to add additional covered conditions for ICR. Heart failure impacts approximately 5.7 million adults, and approximately 80 percent of individuals over age 65 have heart failure. (The majority (86

(e) *Medical record documentation.* The physician may review and verify (sign/date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team including, as applicable, notes documenting the physician's presence and participation in the services.

9. Section 410.40 is amended—

- a. By redesignating paragraphs (a) through (f) as paragraphs (b) through (g), respectively;
- b. By adding new paragraph (a);
- c. In newly redesignated paragraph (b)(1) by removing the reference “paragraphs (d) and (e)” and adding in its place the reference “paragraphs (e) and (f)”; and
- d. By revising newly redesignated paragraphs (e)(2)(i), (e)(3)(i), and (e)(3)(iii) through (v).

The additions and revision reads as follows:

§ 410.40 Coverage of ambulance services.

(a) *Definitions.* As used in this section, the following definitions apply:

Non-physician certification statement means a statement signed and dated by an individual which certifies that the medical necessity provisions of paragraph (e)(1) of this section are met and who meets all of the criteria in paragraphs (i) through (iii) of this definition. The statement need not be a stand-alone document and no specific format or title is required.

(i) Has personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished;

(ii) Who must be employed:

(A) By the beneficiary's attending physician; or

(B) By the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported;

(iii) Is among the following individuals, with respect to whom all Medicare regulations and all applicable State licensure laws apply:

(A) Physician assistant (PA).

(B) Nurse practitioner (NP).

(C) Clinical nurse specialist (CNS).

(D) Registered nurse (RN).

(E) Licensed practical nurse (LPN).

(F) Social worker.

(G) Case manager.

(H) Discharge planner.

Physician certification statement means a statement signed and dated by the beneficiary's attending physician which certifies that the medical necessity provisions of paragraph (e)(1) of this section are met. The statement need not be a stand-alone document and no specific format or title is required.

* * * * *

(e) * * *

(2) * * *

(i) Medicare covers medically necessary nonemergency, scheduled, repetitive ambulance services if the ambulance provider or supplier, before furnishing the service to the beneficiary,

obtains a physician certification statement dated no earlier than 60 days before the date the service is furnished.

* * * *

(3) * *

(i) For a resident of a facility who is under the care of a physician if the ambulance provider or supplier obtains a physician certification statement within 48 hours after the transport.

* * * *

(iii) If the ambulance provider or supplier is unable to obtain a signed physician certification statement from the beneficiary's attending physician, a non-physician certification statement must be obtained.

(iv) If the ambulance provider or supplier is unable to obtain the required physician or non-physician certification statement within 21 calendar days following the date of the service, the ambulance provider or supplier must document its attempts to obtain the requested certification and may then submit the claim. Acceptable documentation includes a signed return receipt from the U.S. Postal Service or other similar service that evidences that the ambulance supplier attempted to obtain the required signature from the beneficiary's attending physician or other individual named in paragraph (e)(3)(iii) of this section.

(v) In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to the contractor. The presence of the physician or non-physician certification statement or signed return receipt does not alone demonstrate that the ambulance transport was medically necessary. All other program criteria must be met in order for payment to be made.

* * * *

10. Section 410.41 is amended by revising the section heading and paragraph (c)(1) to read as follows:

§ 410.41 Requirements for ambulance providers and suppliers.

* * * *

(c) * *

(1) Bill for ambulance services using CMS-designated procedure codes to describe origin and destination and indicate on claims form that the physician certification statement or non-physician certification statement is on file, if required.

* * * *

11. Section 410.49 is amended by revising paragraph (b)(1)(vii) and adding paragraph (b)(1)(viii) to read as follows:

**§ 410.49 Cardiac rehabilitation program and intensive cardiac rehabilitation program:
Conditions of coverage.**

* * * *

(b)* *

(1)* *

(vii) Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks, on or after February 18, 2014 for cardiac rehabilitation and on or after February 9, 2018 for intensive cardiac rehabilitation; or

(b) The Secretary will not pursue sanctions under section 1877(g) of the Act against any party to an arrangement that CMS determines is indistinguishable in all its material aspects from an arrangement with respect to which CMS issued a favorable advisory opinion.

(c) Individuals and entities may rely on an advisory opinion as non-binding guidance that illustrates the application of the physician self-referral law and regulations to the specific facts and circumstances described in the advisory opinion.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

30. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

31. Section 414.601 is amended by adding the following sentence to the end of the section:

§ 414.601 Purpose.

***Section 1834(l)(17) of the Act requires the development of a data collection system to collect cost, revenue, utilization, and other information determined appropriate from providers of services and suppliers of ground ambulance services.

32. Section 414.605 is amended by—

- a. Adding the definition of “Ground ambulance organization” in alphabetical order; and
- b. In the definition of “Paramedic ALS intercept (PI)” by removing the reference “§ 410.40(c)” and adding in its place the reference “§ 410.40(d)”.

The addition reads as follows:

§ 414.605 Definitions.

* * * * *

Ground ambulance organization means a Medicare provider or supplier of ground ambulance services.

* * * *

33. Section 414.610 is amended by adding paragraph (c)(9) to read as follows:

§ 414.610 Basis of payment.

* * * *

(c) * * *

(9) *Payment reduction for failure to report data.* In the case of a ground ambulance organization (as defined at § 414.605) that is selected by CMS under § 414.626(c) for a year that does not sufficiently submit data under § 414.626(b) and is not granted a hardship exemption under § 414.626(d), the payments made under this section are reduced by 10 percent for the applicable period. For purposes of this paragraph, the applicable period is the calendar year that begins following the date that CMS provided written notification to the ground ambulance organization under § 414.626(e)(1) that the ground ambulance did not sufficiently submit the required data.

* * * *

34. Section 414.626 is added to subpart H to read as follows:

§ 414.626 Data reporting by ground ambulance organizations.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Data collection period means, with respect to a year, the 12-month period that reflects the ground ambulance organization's annual accounting period.

Data reporting period means, with respect to a year, the 5-month period that begins the day after the last day of the ground ambulance organization's data collection period.

For a year means one of the calendar years from 2020 through 2024.

Medicare Ground Ambulance Data Collection Instrument means the single survey-based data collection instrument that can be accessed by sampled ambulance organizations under this section via a secure web-based system for reporting data under this section.

(b) *Data collection and submission requirement.* Except as provided in paragraph (d) of this section, a ground ambulance organization selected by CMS under paragraph (c) of this section must do the following:

(1) Within 30 days of the date that CMS notifies a ground ambulance organization under paragraph (c)(3) of this section that it has selected the ground ambulance organization to report data under this section, the ground ambulance must select a data collection period that corresponds with its annual accounting period and provide the start date of that data collection period to the ground ambulance organization's Medicare Administrative Contractor.

(2) Collect during its selected data collection period the data necessary to complete the Medicare Ground Ambulance Data Collection Instrument.

(3) Submit to CMS a completed Medicare Ground Ambulance Data Collection Instrument during the data reporting period that corresponds to the ground ambulance organization's selected data collection period.

(c) *Representative sample.* (1) *Random sample.* For purposes of the data collection described in paragraph (b) of this section, and for a year, CMS will select a random sample of 25 percent of eligible ground ambulance organizations that is stratified based on:

- (i) Provider versus supplier status and ownership (for-profit, non-profit, and government);
- (ii) Service area population density (transports originating in primarily urban, rural, and super rural zip codes); and

(iii) Medicare-billed transport volume categories.

(2) *Selection eligibility.* A ground ambulance organization is eligible to be selected for data reporting under this section for a year if it is enrolled in Medicare and has submitted to CMS at least one Medicare ambulance transport claim during the year prior to the selection under paragraph (b)(1) of this section.

(3) *Notification of selection for a year.* CMS will notify an eligible ground ambulance organization that it has been selected to report data under this section for a year at least 30 days prior to the beginning of the calendar year in which the ground ambulance organization must begin to collect data by posting a list of selected organizations on the CMS webpage and providing written notification to each selected ground ambulance organization via email or U.S. mail.

(4) *Limitation.* CMS will not select the same ground ambulance organization under this paragraph (c) in 2 consecutive years, to the extent practicable.

(d) *Hardship exemption.* A ground ambulance organization selected under paragraph (c) of this section may request and CMS may grant an exception to the reporting requirements under paragraph (b) of this section in the event of a significant hardship, such as a natural disaster, bankruptcy, or similar situation that the Secretary determines interfered with the ability of the ground ambulance organization to submit such information in a timely manner for the data collection period selected by the ground ambulance organization.

(1) To request a hardship exemption, the ground ambulance organization must submit a request form (accessed on the Ambulances Services Center Website (<https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html>) to CMS within 90 calendar days of the date that CMS notified the ground ambulance organization that it would

receive a 10 percent payment reduction as a result of not submitting sufficient information under the data collection system. The request form must include all of the following:

- (i) Ground ambulance organization name.
- (ii) NPI number.
- (iii) Ground ambulance organization address.
- (iv) Chief executive officer and any other designated personnel contact information, including name, e-mail address, telephone number and mailing address (must include a physical address, a post office box address is not acceptable).
- (v) Reason for requesting a hardship exemption.
- (vi) Evidence of the impact of the hardship (such as photographs, newspaper or other media articles, financial data, bankruptcy filing, etc.).
- (vii) Date when the ground ambulance organization would be able to begin collecting data under paragraph (b) of this section.
- (viii) Date and signature of the chief executive officer or other designated personnel of the ground ambulance organization.

(2) CMS will provide a written response to the hardship exemption request within 30 days of its receipt of the hardship exemption form.

(e) *Notification of non-compliance and informal review.* (1) *Notification of non-compliance.* A ground ambulance organization selected under paragraph (c) of this section for a year that does not sufficiently report data under paragraph (b) of this section, will receive written notification from CMS that it will receive a payment reduction under § 414.610(c)(9).

(2) *Informal review.* A ground ambulance organization that receives a written notification under paragraph (e)(1) of a payment reduction under § 414.610(c)(9) may submit a

request for an informal review within 90 days of the date it received the notification by submitting all of the following information:

- (i) Ground ambulance organization name.
- (ii) NPI number.
- (iii) Chief executive officer and any other designated personnel contact information, including name, e-mail address, telephone number and mailing address with the street location of the ground ambulance organization.
- (iv) Ground ambulance organization's selected data collection period and data reporting period.
- (v) A statement of the reasons why the ground ambulance organization does not agree with CMS' determination and any supporting documentation.
- (f) *Public availability of data.* Beginning in 2022, and at least once every 2 years thereafter, CMS will post on its website data that it collected under this section, including but not limited to summary statistics and ground ambulance organization characteristics.
- (g) *Limitations on review.* There is no administrative or judicial review under section 1869 or section 1878 of the Act, or otherwise of the data required for submission under paragraph (b) of this section or the selection of ground ambulance organizations under paragraph (c) of this section.

35. Section 414.1305 is amended by—

- a. Adding the definition of “Aligned Other Payer Medical Home Model” in alphabetical order;
- b. Revising the definition of “Hospital-based MIPS eligible clinician”;
- c. Adding the definition of “MIPS Value Pathway” in alphabetical order; and

* * * *

63. Section 424.518 is amended by adding paragraphs (b)(1)(xii) and (xiii) and (c)(1)(iv) to read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers.

* * * *

(b) * *

(1) * *

(xii) Prospective (newly enrolling) opioid treatment programs that have been fully and continuously certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) since October 23, 2018.

(xiii) Revalidating opioid treatment programs.

* * * *

(c) * *

(1) * *

(iv) Prospective (newly enrolling) opioid treatment programs that have not been fully and continuously certified by SAMHSA since October 23, 2018.

* * * *

64. Section 424.520 is amended by revising paragraph (d) introductory text to read as follows:

§ 424.520 Effective date of Medicare billing privileges.

* * * *

(d) *Physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, and opioid treatment programs.* The effective date for

billing privileges for physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, and opioid treatment programs is the later of--

* * * * *

65. Section 424.521 is amended by revising the section heading and paragraph (a) introductory text to read as follows:

§ 424.521 Request for payment by physicians, non-physician practitioners, physician and non-physician organizations, ambulance suppliers, and opioid treatment programs.

(a) Physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, and opioid treatment programs may retrospectively bill for services when the physician, non-physician practitioner, physician or non-physician organization, ambulance supplier, or opioid treatment program has met all program requirements, including State licensure requirements, and services were provided at the enrolled practice location for up to --

* * * * *

66. Section 424.530 is amended by adding paragraph (a)(15) to read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

(a) * * *

(15) *Patient harm.* (i) The physician or other eligible professional (as that term is defined in 1848(k)(3)(B) of the Act) has been subject to prior action from a State oversight board, Federal or State health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible