

## Qualifying Payment Amount Calculation Methodology

45 CFR 149.140

**June 2022** 

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#### Overview

- The qualifying payment amount (QPA) is the basis for determining individual cost sharing for items and services covered by the balance-billing protections in the No Surprises Act (NSA), under certain circumstances.
  - Cost-sharing for emergency items and services and non-emergency items and services furnished by an out-of-network provider in an innetwork facility must be based on the lesser of billed charges or the QPA, where an All-Payer Model Agreement under section 1115A of the Soc. Sec. Act or a specified state law does not apply.
  - Cost-sharing for air ambulances services must be based on the lesser of billed charges or the QPA
- Certified Independent Dispute Resolution (IDR) entities are required to consider the QPA when selecting between the offer submitted by a plan or issuer and the offer submitted by a facility or provider or provider of air ambulance services when determining the total out-of-network payment rate for items and services subject to the federal IDR process.

### **QPA** Defined

The QPA for a given item or service is generally the median contracted rate on January 31, 2019 for the same or similar item or service, increased for inflation

#### **Median Contracted Rate**

The median contracted rate for an item or service is determined by:

- Identifying the contracted rates of all plans of the plan sponsor (or
  of the administering entity, if applicable) or all coverage offered by
  the issuer in the same insurance market for the same or similar
  item or service that is provided by a provider in the same or
  similar specialty or facility of the same or similar facility type and
  provided in the geographic region in which the item or service is
  furnished.
- Arranging the contracted rates from least to greatest, and selecting the middle number (or the average of the middle two numbers, if there are an even number of contracted rates).

#### "Contracted Rate" Defined

 The contracted rate is the total amount (including) cost sharing) that a group health plan or health insurance issuer has contractually agreed to pay a participating provider, facility, or provider of air ambulance services for covered items and services, whether directly or indirectly, including through a third-party administrator (TPA) or pharmacy benefit manager (PBM).

#### **Contracted Rate – Rules & Exclusions**

- The amount negotiated under each contract is treated as a separate amount.
  - Excludes rates paid under single case agreements, letters of agreement, or similar arrangements between a provider, facility, or provider of air ambulance services and a plan or issuer, used to supplement the network of the plan for a specific enrollee, participant, or beneficiary in unique circumstances.
- The rate negotiated under a contract constitutes a single contracted rate regardless of the number of claims paid at that contracted rate.

#### **Contracted Rate – Other Rules**

- If a plan or issuer has:
  - separate contracts with individual providers → rate under each contract constitutes a single contracted rate (even if the same rate is paid to other providers under separate contracts).
  - a single contract with a provider group or facility, with the same negotiated rate applying to all providers in the group/facility → rate negotiated with that provider group or facility is treated as a single contracted rate.
  - a single contract with multiple providers, with separate negotiated rates with each particular provider → each unique contracted rate constitutes a single contracted rate for purposes of determining the median contracted rate.

### "Same Insurance Market"

- "Insurance market" is defined as:
  - Individual market (excludes short-term, limited-duration insurance).
  - Small group market.
  - Large group market.
- For self-insured group health plans, "insurance market" means:
  - o all self-insured group health plans (other than account-based plans and plans that consist solely of excepted benefits) of the plan sponsor, or
  - at the option of the plan sponsor, all self-insured group health plans administered by the same entity (including a TPA contracted by the plan) that's responsible for calculating the QPA on behalf of the plan.
- Any plan or coverage that is not a "group health plan" or "group or individual health insurance coverage" offered by a "health insurance issuer," as those terms are defined in the Code, ERISA, and the PHS Act, such as a Medicare Advantage or Medicaid managed care organization plan, must also not be included in any insurance market for purposes of determining the QPA.
- Relevant market is determined irrespective of the state.
- All markets exclude coverage that consists solely of excepted benefits

#### "Same or Similar Item or Service"

- Defined as a health care item or service billed under the same service code, or a comparable code under a different procedural code system.
- Service code: the code that describes an item or service, including a Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) code.

## "Same or Similar Item or Service" – Modifiers

- Modifiers: codes that are applied to the service code to provide a more specific description of the furnished item or service and that may adjust the payment rate or affect the processing or payment of the code billed.
- Median contracted rates must be calculated separately for CPT code modifiers that distinguish the professional services component ("26") from the technical component ("TC").
- If application of a modifier causes contracted rates to vary, the plan or issuer must calculate a separate median contracted rate for each such service code-modifier combination.
- Modifiers that don't cause contracted rates to vary must not be taken into account when calculating the median contracted rate.

# "Provider in the Same or Similar Specialty"

- Defined as the practice specialty of a provider, as identified by the plan or issuer consistent with the plan's or issuer's usual business practice.
- With respect to air ambulance services, all providers of air ambulance services are considered to be a single provider specialty.
- If a plan or issuer has contracted rates for a service code that vary based on provider specialty, the median contracted rate is calculated separately for each provider specialty.

# "Facility of the Same or Similar Facility Type"

- Defined to mean, with respect to emergency services, either an emergency department (ED) of a hospital or an independent freestanding emergency department (IFED).
- If a plan's or issuer's contracted rates for **emergency services** vary based on the type of facility (that is, whether a facility is a hospital ED or an IFED, the median contracted rate is calculated separately for each facility type.
- Note: Plans and issuers may not separately calculate a median contracted rate based on other characteristics of facilities that might cause contracted rates to vary, such as whether a hospital is an academic medical center or teaching hospital.

## **Geographic Region**

	Non-air ambulance items and services		Air ambulance services	
Primary definition	One region for each MSA in the state	One region consisting of all other portions of the state	One region consisting of all MSAs in the state	One region consisting of all other portions of the state
First alternative	One region consisting of all MSAs in the state	One region consisting of all other portions of the state	One region consisting of all MSAs in the Census division	One region consisting of all other portions of Census division
Second alternative	One region consisting of all MSAs in the Census division	One region consisting of all other portions of the Census division		

- If a plan or issuer does not have sufficient information to calculate a median contracted rate for the geographic regions under the primary definition, geographic regions are defined according to the first alternative definition.
- If the plan or issuer still does not have sufficient information after applying these broader regions, geographic regions are defined using the second alternative definition (N/A for air ambulance services).

## Geographic Region (continued)

- Note: MSAs that cross state boundaries are divided between the respective states, with all the counties in a particular MSA in each state counted as a geographic region.
- Geographic region to be applied for air ambulance services is determined by the **point of pickup**, meaning the location of the individual at the time the individual is placed on board the air ambulance.

# Non-Fee-for-Service Contractual Arrangements

- QPA methodology establishes an approach for calculating a median contracted rate where
  payment for an item or service is not fully on a fee-for-service basis (e.g., under bundled and
  fully- or partially-capitated arrangements).
- **General approach:** The plan or issuer must calculate a median contracted rate for each item or service using the **underlying fee schedule rates** (if available) for the relevant items and services.
  - Underlying fee schedule rate: the rate for a covered item or service that a group health plan or health insurance issuer uses to determine an individual's cost-sharing liability for the item or service, when that rate is different from the contracted rate.
- Alternative approach: If there is no underlying fee schedule rate, the plan or issuer must calculate the median contracted rate using a **derived amount**, which is the price that a plan or issuer assigns an item or service for the purpose of internal accounting, reconciliation with providers, or for the purpose of submitting data in accordance with 45 CFR 153.710(c).
- When calculating median contracted rates, plans and issuers **must exclude** risk sharing, bonus, or penalty, and other incentive-based and retrospective payments or payment adjustments.

## **Indexing: Overview**

- In cases where the median contracted rate is determined using 1/31/2019 contracted rates:
  - o To calculate QPA for items/services furnished during 2022: increase the median contracted rate as of 1/31/2019 by the percentage increase in the consumer price index for all urban consumers (U.S. city average) (CPI–U) over 2019, the percentage increase over 2020, and the percentage increase over 2021.
  - To calculate QPA for items/services furnished during 2023 or a subsequent year: the QPA for 2022 is then adjusted annually by the annual increase in the CPI–U.
- Plans and issuers will calculate the increases using the factors determined by the Treasury Department and the IRS, and published in guidance by the IRS. The percentage increase for any year is calculated by using the CPI–U published by the Bureau of Labor Statistics (DOL).
- For this purpose, the CPI–U for each calendar year is the average of the CPI–U as
  of the close of the 12-month period ending on 8/31 of the calendar year, rounded
  to 10 decimal places.

## Indexing: Special Rules for Unit-Based Services

- Special rules apply when calculating the QPA for items or services for which a plan or issuer generally determines the reimbursement level for the same or similar items or services by multiplying the contracted rate by another unit, such as time or mileage.
- Rule: The QPA for unit-based items and services is calculated by determining the median contracted rate for the item or service, indexing that median amount in accordance with the otherwise applicable rules regarding indexing, and then applying the pertinent multipliers.

### **Indexing: Anesthesia Services**

- For anesthesia services furnished during 2022, the QPA is calculated by taking the median contracted rate for the anesthesia conversion factor (determined in accordance with the methodology for calculating median contracted rates for service code-modifier combinations) for the same or similar item or service as of 1/31/2019, and increasing that amount to account for changes in the CPI–U.
- This amount is referred to as the indexed median contracted rate, and it is multiplied by the sum of the following three factors in order to calculate the QPA:
  - (1) the **base unit** for the anesthesia service code
  - (2) the time unit, and
  - (3) the physical status modifier unit.
- For anesthesia services furnished during 2023 or a subsequent year, the QPA is calculated by taking the indexed median contracted rate for the anesthesia conversion factor, and adjusting that amount by the percentage increase in the CPI– U over the previous year. The indexed median contracted rate is then multiplied by the sum of the base unit, time unit, and physical status modifier units for the participant, beneficiary, or enrollee.

## **Indexing: Air Ambulance Services**

Payers often reimburse air ambulance services in part by using air mileage service codes (A0435 and A0436) and reimbursement levels that reflect the number of miles an individual is transported by the air ambulance, which are referred to as loaded miles. Payment amounts are calculated as:

(negotiated rate for the service code, referred to as the **air mileage rate**) X (number of loaded miles).

- The QPA for air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2022 is calculated as follows:
  - Step 1: Increase the median contracted rate to account for changes in the CPI–U. This
    amount is referred to as the indexed median air mileage rate.
  - Step 2: Multiply (indexed median air mileage rate) by (number of loaded miles).
- The QPA for air ambulance services billed using service codes A0435 and A0436 that are furnished during 2023 or a subsequent year is calculated as follows:
  - Step 1: Increase the indexed median air mileage rate determined for such services furnished in the preceding year.
  - Step 2: Multiply (indexed median air mileage rate) by (number of loaded miles).

#### **Cases With Insufficient Information**

- An alternative process is used to determine the QPA in cases where a group health plan or health insurance issuer offering group or individual health insurance coverage lacks sufficient information to calculate the median of contracted rates in 2019, as well as for newly covered items or services in the first coverage year after 2019.
- In cases in which a plan or issuer does not have "sufficient information" to calculate a median contracted rate, the plan or issuer must determine the QPA using an eligible database (discussed in later slides).

#### **Sufficient Information**

- Rule: A plan or issuer has sufficient information to calculate the median of contracted rates for an item or service if the plan or issuer has at least three contracted rates on 1/31/2019.
- Where a plan or issuer does not have sufficient information to calculate the median contracted rate based on 1/31/2019 contracted rates (or for new plans and coverage or new service codes) but later gains sufficient information, the plan or issuer must calculate the QPA using the median contracted rate for the first sufficient information year.

#### First Sufficient Information Year

#### First sufficient information year is defined as follows:

- (1) in the case of an item and service for which a plan or issuer does not have sufficient information to calculate the median of contracted rates in 2019, the first year after 2022 for which the plan or issuer has sufficient information to calculate the median of contracted rates in the year immediately preceding that first year after 2022; and
- (2) in the case of a **newly covered item or service**, the **first year after the first coverage year** for such item or service for which the plan or issuer has **sufficient information to** calculate the median of the contracted rates in the year immediately preceding that first year.

# First Sufficient Information Year (continued)

- In cases where contracted rates for a year after 2019 must be used to calculate the median contract rate, a plan or issuer will be considered to have sufficient information to calculate the median contracted rate for a year if **both** of the following conditions are met:
  - the plan or issuer has at least three contracted rates on January 31 of the year immediately preceding that year; and
  - the contracted rates account (or are reasonably expected to account) for at least 25 percent of the total number of claims paid for the item/service for that year with respect to all plans of the sponsor (or administering entity, if applicable) or all coverage offered by the issuer in the same insurance market.

## **Database Eligibility Requirements**

- Where a plan or issuer does not have sufficient information to calculate a median contracted rate, the plan or issuer must determine the QPA using an eligible database.
- A third-party database may be an eligible database if it satisfies all of the following conditions:
  - No conflicts of interest.
  - Has sufficient information regarding in-network allowed amounts paid to a health care providers or facilities for relevant items/services furnished in the applicable geographic region.
  - Has the ability to distinguish amounts paid to participating providers and facilities by commercial payers from all other claims data.
- State all-payer claims databases have been deemed categorically eligible.

## Database Eligibility Requirements – Conflicts of Interest

- As noted in the previous slide, an eligible database is required to be free from any conflicts of interest. Specifically, the database or the organization maintaining the database cannot be affiliated with, or owned or controlled by, any health insurance issuer, or a health care provider, facility, or provider of air ambulance services, or any member of the same controlled group as, or under common control with, any such entity.
- For purposes of applying the controlled group rules to eligible databases, a controlled group means a group of two or more persons that is treated as a single employer under Code sections 52(a), 52(b), 414(m), or 414(o).

# Determining the QPA Using an Eligible Database

- To calculate the QPA for an item or service furnished during 2022 (or for newly covered items or services, in the first coverage year) using an eligible database, a plan or issuer must:
  - First, identify the rate in the database that is equal to the median of the in-network allowed amounts for the same or similar item or service in the geographic region in the year immediately preceding the year in which the item or service is furnished (or for a newly covered item or service, the year immediately preceding the first coverage year).
  - Then, increase the median in-network allowed amount by the percentage increase in the CPI–U over the preceding year.
- For each subsequent year before the first sufficient information year, the plan or issuer must increase the QPA applicable in the immediately preceding year by the percentage increase in the CPI–U over the preceding year.

# Determining QPA Using an Eligible Database (continued)

- Consistency requirement: A plan or issuer that uses a
  database to determine the QPA for an item or service must
  use the same database to determine the QPA for that item or
  service through the last day of the calendar year.
  - If a different database is selected for some items or services, the basis for that selection must be one or more factors not directly related to the rate of those items or services (e.g., the sufficiency of data for those items or services).
- Plan or issuer is responsible for the costs associated with using an eligible database to determine the QPA.

## **New Plans or Coverage**

- In cases where a sponsor of group health plan or a health insurance issuer is **newly** offering a plan or coverage in a geographic region in a year after 2019:
  - o if the plan or issuer otherwise has sufficient information to calculate a median contracted rate in 2019 in the geographic region where the item or service is furnished (e.g., where the sponsor or issuer has sufficient existing provider contracts under other current coverage in the geographic region), the QPA is determined using the standard methodology.
  - o if the plan or issuer does not have sufficient information to calculate a median contracted rate in 2019 in the geographic region (e.g., where the sponsor or issuer did not offer any plan or coverage in 2019), for items and services in the first year in which the plan or coverage is offered in the geographic region, the QPA is determined according to the rules that generally apply when there's insufficient information to calculate a median contracted rate, or for newly covered items and services, including the use of an eligible database.
- To calculate the QPA for items and services furnished in a subsequent year, the plan
  or issuer must increase the QPA for items or services furnished in the immediately
  preceding year by the percentage increase in the CPI–U over the previous year.

#### **New Service Code**

- Defined as a service code that was created or substantially revised in a year after 2019.
- In situations in which a plan or issuer is billed for a covered item or service using a new service code, the plan or issuer must determine the QPA as follows:
  - Step 1: Identify a reasonably related service code that existed in the immediately preceding year (e.g., another service code within the same family of codes, or a code for services that represent similar relative value units).

## **New Service Code (continued)**

- Step 2: Calculate the applicable relativity ratio.
  - If the Medicare program has established a payment rate for an item or service billed under the new service code, the plan or issuer must: calculate the ratio of the Medicare payment rate for the item or service billed under the new service code compared to the Medicare payment rate for the item or service under the related service code (with both rates disregarding any adjustments for value-based purchasing arrangements).
  - If the Medicare program has **not** established a payment rate for an item or service billed under the new service code, the plan or issuer must calculate the ratio of the rate that the plan or issuer pays for an item or service billed under the new service code compared to the rate that the plan or issuer pays for an item or service under the related service code.
- Step 3: Multiply the ratio in step 2 by the QPA for the related service code for the year in which the item or service is furnished.

# Information To Be Shared About the QPA: Required Disclosures

- The July 2021 interim final rules require that plans and issuers make certain disclosures with each initial payment or notice of denial of payment, and that plans and issuers must provide additional information upon request of the provider, facility, or provider of air ambulance services.
- First, a plan or issuer must provide the QPA for each item or service involved.
- Second, a plan or issuer must provide a statement certifying that:
  - (1) The QPA applies for purposes of the recognized amount (or, in the case of air ambulance services, for calculating the participant's, beneficiary's, or enrollee's cost sharing), and
  - (2) each QPA shared with the provider, facility, or provider of air ambulance services was determined in compliance with the methodology outlined in the July 2021 interim final rules.
- Third, a plan or issuer must provide a statement informing the provider, facility, or provider of air ambulance services that they may initiate the 30-day open negotiations period, and if that fails to produce a determination, they may initiate the federal IDR process within 4 days of the end of open negotiations.
- Fourth, the plan or issuer must also provide contact information for the appropriate office or person to initiate open negotiations.

# Information to Be Shared About the QPA Upon Request

- In a timely manner upon request of the provider, facility, or provider of air ambulance services, a plan or issuer must provide the following:
  - Information about whether the QPA includes contracted rates that were not set on a fee-for-service basis for the specific items and services at issue and whether the QPA was determined using underlying fee schedule rates or a derived amount.
  - If an eligible database was used to determine the QPA, information to identify which database was used to determine the QPA.
  - If a related service code was used to determine the QPA for a new service code, information to identify which related service code was used.
  - If applicable, a statement that the plan's or issuer's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments for the items and services involved that were excluded to calculate the QPA.

## Glossary

- cost sharing the amount a participant, beneficiary, or enrollee is responsible for paying for a covered item
  or service under the terms of the group health plan or health insurance coverage.
- **derived amount** the price that a plan or issuer assigns an item or service for the purpose of internal accounting, reconciliation with providers, or for the purpose of submitting data in accordance with the requirements of 45 CFR 153.710(c).
- modifier code applied to a service code that provides a more specific description of the furnished item or service and that may adjust the payment rate or affect the processing or payment of the code billed.
- **new service code** –a service code that was created or substantially revised in a year after 2019.
- qualifying payment amount In general, for a given item or service, the QPA is the median of the contracted rates on January 31, 2019, for the same or similar item or service, increased for inflation.
- recognized amount basis for determining individual cost sharing for certain services covered by the balance billing provisions of the No Surprises Act. Defined as (1) an amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act; (2) if there is no applicable All-Payer Model Agreement, an amount determined by a specified state law; or (3) if there is no applicable All-Payer Model Agreement or specified state law, the lesser of the amount billed by the provider or facility or the QPA.
- underlying fee schedule rate the rate for a covered item or service from a particular participating provider, providers, or facility that a group health plan or health insurance issuer uses to determine a participant's, beneficiary's, or enrollee's cost-sharing liability for the item or service, when that rate is different from the contracted rate.

## **QPA Audit Authority**

Statutory authority to conduct audits: 42 U.S.C. § 300gg-111(a)(2)

#### (A) Audit process

- (i) In general. Not later than October 1, 2021, the Secretary, in consultation with the Secretary of Labor and the Secretary of the Treasury, shall establish through rulemaking a process, in accordance with clause (ii), under which group health plans and health insurance issuers offering group or individual health insurance coverage are audited by the Secretary or applicable State authority to ensure that-
  - (I) such plans and coverage are in compliance with the requirement of applying a qualifying payment amount under this section; and
  - (II) such qualifying payment amount so applied satisfies the definition under paragraph (3)(E) with respect to the year involved, including with respect to a group health plan or health insurance issuer described in clause (ii) of such paragraph (3)(E).

## **QPA Audit Authority (continued)**

#### (ii) Audit samples

Under the process established pursuant to clause (i), the Secretary-

- (I) shall conduct audits described in such clause, with respect to a year (beginning with 2022), of a sample with respect to such year of claims data from not more than 25 group health plans and health insurance issuers offering group or individual health insurance coverage; and
- (II) may audit any group health plan or health insurance issuer offering group or individual health insurance coverage if the Secretary has received any complaint or other information about such plan or coverage, respectively, that involves the compliance of the plan or coverage, respectively, with either of the requirements described in subclauses (I) and (II) of such clause.

Note: state regulators enforcing the qualifying payment amount provisions may call QPA audits of plans and issuers within their jurisdiction. Plans and issuers should check with such enforcing states regarding their processes

### **QPA Audit Regulation**

- Implementing regulation: 45 C.F.R. § 149.140(f)
- Audits. The procedures described in part 150 of this subchapter apply with respect to ensuring that a plan or coverage is in compliance with the requirement of applying a qualifying payment amount under this subpart and ensuring that such amount so applied satisfies the requirements under this section [regarding the QPA methodology], as applicable.

#### **QPA Audit Scope**

 The Audit's scope is applicable to services and items covered by group health plans or health insurance issuers offering group or individual health insurance coverage, but does not include short-term, limited duration insurance, health reimbursement arrangements, and other account-based plans, or excepted benefit insurance plans.

#### **QPA Audit Process**

- A call letter will be sent notifying the plan sponsor or issuer that a QPA audit has commenced and requesting the initial audit data and documents.
- A pre-examination meeting will be conducted to go over the data and documents requested, set expectations for the audit, arrange any security access or training required if examiners are to access systems directly, and to answer questions from the plan or issuer.

### **QPA Audit Process (continued)**

- Samples will be selected and additional documents will be requested and reviewed for those samples from the plan or issuer. The documents include claims-related items, information about the QPA sent with initial payments or notices of denial of payment, and other items demonstrating regulatory compliance.
- Questions to the plan or issuer will be sent through a request for information (RFI) throughout the audit process.
- Preliminary findings of potential violations will be provided to the plan sponsor or issuer through a Criticism prior to the draft final report.
  - The plan sponsor or issuer will have an opportunity to provide additional information if they disagree with the preliminary findings.

# QPA Audit Data and Document Requests

- A comprehensive list of all insurance markets (as defined in 45 CFR 149.140(a)(8)) in which the Plan or Issuer offers coverage and each plan offered in such market. For each plan on the list, provide documents related to each plan's coverage and benefits, which includes, but is not limited to, the policy, certificate, or contract of insurance, and schedule of benefits.
- A narrative describing the Plan's or Issuer's QPA calculation methodology demonstrating compliance. The narrative should be in a step-by-step format and should be supplemented with any supporting documentation that is necessary to provide a clear and comprehensive explanation. This includes any QPAs for which the plan sponsor or issuer had insufficient information to calculate the median of contracted rates for items and services furnished in 2022.

# QPA Audit Data and Document Requests (continued)

- A read-only access, remote access, or other reasonable substitute, to the claims administration system applicable during the Audit period that provides access to claims for which the requirement to apply a QPA applies. If unable to provide such access, provide:
  - A claims data file, in the format prescribed in a spreadsheet that be will be provided with the call letter, that includes all paid, denied, and pending claims for which the requirement to apply a QPA applies, and appeals of adverse benefit determinations for all such claims for all applicable plans effective during the Audit period.
  - A complete data file, in the format prescribed in the spreadsheet that will be provided with the call letter, that includes all QPAs calculated, whether or not associated with a claim, during the Audit period.

# QPA Audit Data and Document Requests (continued)

- Provide claims handling manuals, internal bulletins, medical criteria used, and guidelines the [Plan/Issuer] utilized at any point during the Audit period that address how the [Plan/Issuer] identifies claims for which the requirement to apply a QPA applies, and how the [Plan/Issuer] applies the QPA to such claims.
- A complete complaint log, or similar documentation, that identifies any entries with respect to QPAs as well as the corresponding complaint file.

#### **QPA Audit Process: Conclusion**

- A draft final report will be provided to the plan sponsor or issuer once our review is complete and all Criticisms have been responded to by the plan sponsor or issuer.
- The plan sponsor or issuer will have 30 calendar days from the date of receipt of the draft final report to:
  - Concur with CMS's position(s) as outlined in the report,
     explaining the plan of correction to be implemented.
  - Dispute CMS's position(s), clearly outlining the basis for its dispute and submitting illustrative examples where appropriate.

# QPA Audit Process: Conclusion (continued)

CMS will provide a response to each examination issue in its final report. CMS's reply will consist of one of the following:

- Concurrence with the issuer's or plan's
- Approval of the issuer's or plan's proposed plan of correction.
- Conditional approval of the issuer's or plan's proposed plan of correction, which will include any modifications CMS requires.
- Notice to the issuer or plan that there exists a potential violation of PHS Act requirements.

### **Civil Money Penalty Authority**

Statutory authority to impose civil money penalty: 42 U.S.C. § 300gg-22(b)(2)

- (A) In general. Subject to the succeeding provisions of this subsection, any non-Federal governmental plan that is a group health plan and any health insurance issuer that fails to meet a provision of this part or part D applicable to such plan or issuer is subject to a civil money penalty under this subsection.
- (B) Liability for penalty In the case of a failure by—
  - (i) a health insurance issuer, the issuer is liable for such penalty, or
  - (ii) a group health plan that is a non-Federal governmental plan which is-
    - (I) sponsored by 2 or more employers, the plan is liable for such penalty, or
    - (II) not so sponsored, the employer is liable for such penalty.

### **Civil Money Penalty Regulation**

Regulations implementing civil money penalty authority for violations of provisions under PHS Act title XXVII Part D (45 CFR)

§ 150.315: A civil money penalty for each violation of 42 U.S.C. 300gg et seq. may not exceed \$100 as adjusted annually under 45 CFR part 102 for each day, for each responsible entity, for each individual affected by the violation. Penalties imposed under this part are in addition to any other penalties prescribed or allowed by law.

§§ 150.317 - 323: provide for the factors used to determine the civil money penalty, including mitigating circumstances, aggravating circumstances, and other matters of justice to be considered in setting the civil money penalty.

# Civil Money Penalty Regulation (continued)

#### § 150.341

- (a) Circumstances under which a civil money penalty is not imposed. CMS does not impose any civil money penalty on any failure for the period of time during which none of the responsible entities knew, or exercising reasonable diligence would have known, of the failure. CMS also does not impose a civil money penalty for the period of time after any of the responsible entities knew, or exercising reasonable diligence would have known of the failure, if the failure was due to reasonable cause and not due to willful neglect and the failure was corrected within 30 days of the first day that any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that the failure existed.
- (b) Burden of establishing knowledge. The burden is on the responsible entity or entities to establish to CMS's satisfaction that no responsible entity knew, or exercising reasonable diligence would have known, that the failure existed.

# Civil Money Penalty Regulation (continued)

§§ 150.343 - 347: requires CMS to send a notice of penalty to the responsible party with specific information, provides a right to the responsible party to initiate an appeal of the civil money penalty under 45 CFR § 150.401, et seq., and sets out how CMS may proceed if the responsible party does not submit an appeal within 30 days of the issuance of the notice of civil money penalty.

### **Civil Money Penalty Process**

CMS will go through the process of determining whether a civil money penalty is to be assessed if a violation is found during a QPA audit.

The civil money penalty will be determined based on the factors permitted for consideration, including mitigating and aggravating circumstances, and other matters as justice may require.

A notice of civil money penalty will be sent to the responsible party. That party will have the right to appeal.

If the appeal is not received within 30 days of notice to the responsible party, CMS will send a notice to the responsible party with the final civil money penalty determination and how the plan sponsor, employer, or issuer can satisfy the judgement.

#### **Contacts regarding QPA Audits**

- CMS currently contracts with Examination Resources to assist with conducting the QPA Audits. You will receive information on how to contact Examination Resources in the QPA Audit call letter.
- You can direct general questions regarding QPA audits to QPA AuditTeam@cms.hhs.gov.