

Risk Assessment Tool for Evaluating COVID-19 Flexibilities and Waivers

Thursday, July 15, 2021

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Risk Assessment Tool for Evaluating COVID-19 Flexibilities and Waivers





Introduction

 Discuss why risk assessments are an important tool when evaluating program integrity (PI) risks related to COVID-19 waivers and flexibilities



- Describe the GAO Fraud Risk Management Framework and risk assessment process, and how they can be leveraged broadly, beyond fraud, to support states' COVID-19
 PI work in a variety of areas, using beneficiary eligibility as an example.
- Provide templates for use in conducting risk assessments and demonstrate how-they can be applied

Discussion and questions



Why Leverage Risk Assessments to Support **Evaluation of PI Risks Related to COVID-19 Waivers** and Flexibilities?



Why Risk Assessments? Why Now?

- Risk assessments are valuable tools that can support states to evaluate potential program integrity risks created by COVID-19 flexibilities and waivers, and strategically target resources to resume normal operations and mitigate new or existing risks.
- For example, a risk assessment can help a Medicaid agency plan for how they will process a large backlog of case actions associated with the Families First Coronavirus Response Act (FFCRA) continuous enrollment requirement, including ensuring timely redeterminations and preventing inappropriate terminations.
- This presentation illustrates the risk assessment process through a potential eligibility risk found with the FFCRA. Appendix B provides a list of other potential topics that may also benefit from a program integrity risk assessment.



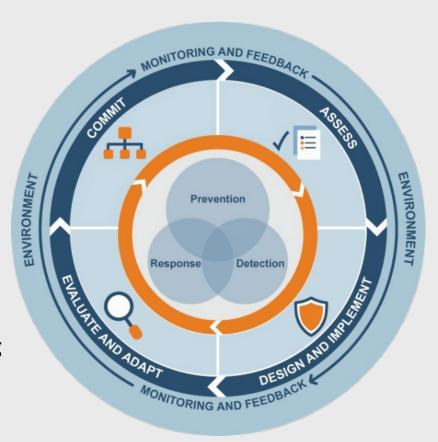
Approaches to Support Evaluation of Program Integrity Risks Related to COVID-19 Waivers and Flexibilities



GAO Fraud Risk Management Framework

A framework for managing fraud risks in federal programs

- Published in 2015 (GAO-15-593SP¹) to support program managers in developing or enhancing efforts to combat fraud in a strategic, risk-based manner.
- Can be leveraged to support program integrity efforts broadly, not just fraud.
- Identifies leading practices and conceptualizes these practices into a riskbased framework.
- Provides a structured approach to conducting risk assessments to support ongoing identification and mitigation of program vulnerabilities.







GAO Fraud Risk Management Framework

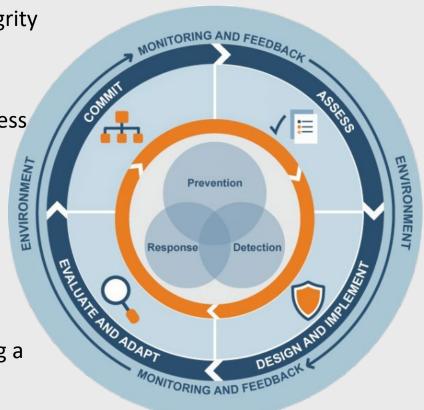
Consists of four components for effectively managing fraud risks

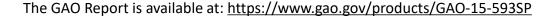
1. Commit—Commit to combating program integrity risks by creating an organizational culture and structure conducive to risk management.

Assess—Plan regular risk assessments and assess risks to determine a risk profile.

3. Design and Implement—Design and implement a strategy with specific control activities to mitigate assessed risks and collaborate to help ensure effective implementation.

4. Evaluate and Adapt—Evaluate outcomes using a risk-based approach and adapt activities to improve risk management.





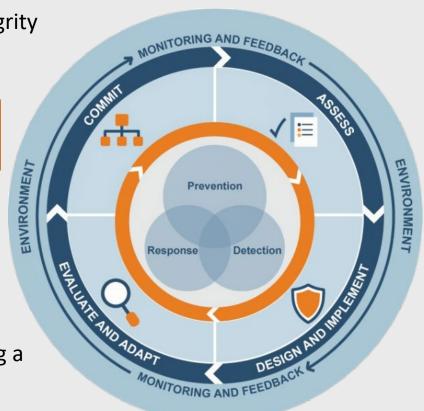


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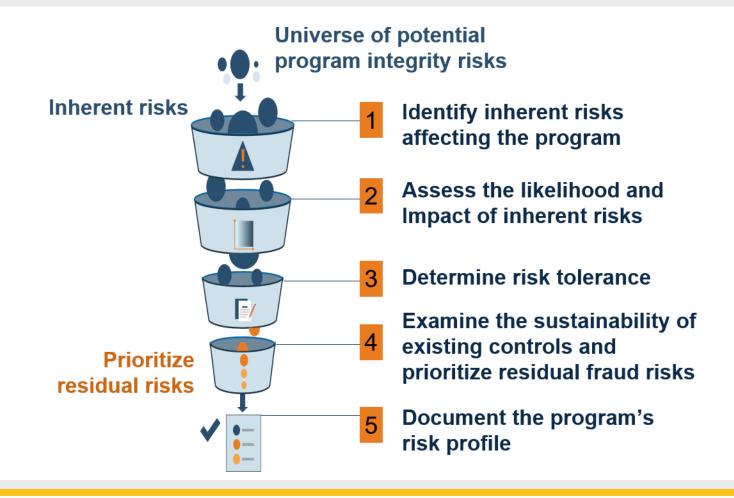


Program Integrity Risk Assessment Overview

What is the process and how is it useful?

- A risk assessment is a strategic, risk-based approach to managing program vulnerabilities and risks and developing effective program integrity controls.
- Involves reviewing internal and external actual or potential threats across the breadth of the Program and assigning a priority to them based on:
 - Likelihood they will happen
 - Negative impact that will result when they do happen
 - The suitability of existing controls for those risks
 - Agency's tolerance for the risk remaining despite existing controls
- The results of the assessment are then documented in a risk profile.







Assessing Program Integrity Risks

Leading Practices for Planning and Conducting Risk Assessments

- Plan regular risk assessments that are tailored to the Program.
 - Plan to conduct risk assessments at regular intervals and when there are changes to the program or operating environment.
 - Identify specific tools, methods, and sources for gathering information about risks, including data on schemes and trends from monitoring and detection activities.
 - Involve relevant stakeholders (e.g., internal and external individuals with in-depth knowledge of your Medicaid operations and organizational mission) in the assessment process, including individuals responsible for the design and implementation of controls.
- Identify and assess risks to determine the program's risk profile.
 - Assess the likelihood and impact of inherent risks by gathering input from qualified specialists (e.g., statisticians) and considering nonfinancial impact of risks such as impact on reputation and compliance with laws, regulations, and standards.
 - Determine risk tolerance.
 - Examine the suitability of existing controls and prioritize residual risks.
 - Document the program's risk profile.



1. Identify inherent risks affecting the program

- Determine where risks can occur and the types of internal and external risks the program faces.
- Methods may include qualitative and/or quantitative ranking activities, forecasting and strategic planning, and consideration of deficiencies identified through audits and other assessments.
- May require engagement with a range of stakeholders to bring diverse perspectives that can identify all potential risks.
- May also involve a variety of activities such as staff interviews, environmental scans, and review of program audits and evaluation reports to ensure a comprehensive assessment.



2. Assess the likelihood and impact of inherent risk

- Involves assessing each inherent risk and assigning a risk score based on the risk's likelihood and impact.
 - States may consider both financial and nonfinancial impact of the risks (e.g., beneficiary harm, likelihood).
- May be analyzed on an individual basis or grouped into categories with related risks and analyzed collectively.
- Methodology used can vary based on factors including a state's resources and differences in approaches to qualitatively and quantitatively defining risk tolerances.



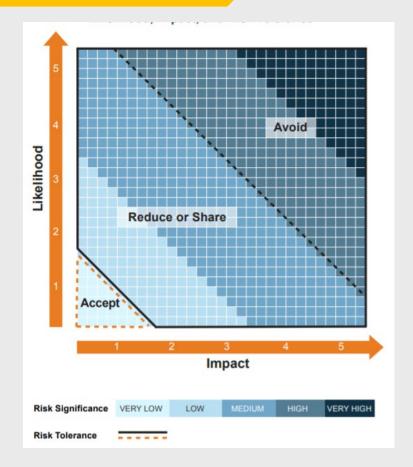
3. Determine risk tolerance

- In general, the goal of risk management is to achieve as low of a risk level as possible; however, it is generally difficult to eliminate all risk. Understanding that not all risk can be eliminated in most cases, risk tolerance represents the level of risk an entity will accept when trying to achieve a goal.
 - This is an essential step when determining which risks to address and prioritize.
 - Requires engagement with management to determine what level of risk tolerance is acceptable for each risk/vulnerability.
- Should be defined using both specific and measurable terms so they are clearly stated and can be measured; can use either qualitative or quantitative terms.
- Management should consider risk tolerances in the context of applicable laws, regulations, and standards as well as the state's standards of conduct, oversight structure, organizational structure, and expectations of competence.



4. Examine existing controls and prioritize residual risks

- Consider extent to which existing control activities mitigate the impact of inherent risks and identify remaining risks (e.g., residual risks).
- Prioritize residual risks and identify additional controls to mitigate the likelihood and impact of residual risks that exceed risk tolerance.
- Identify responsible internal and external entities, or "owners" of risk mitigation activities.





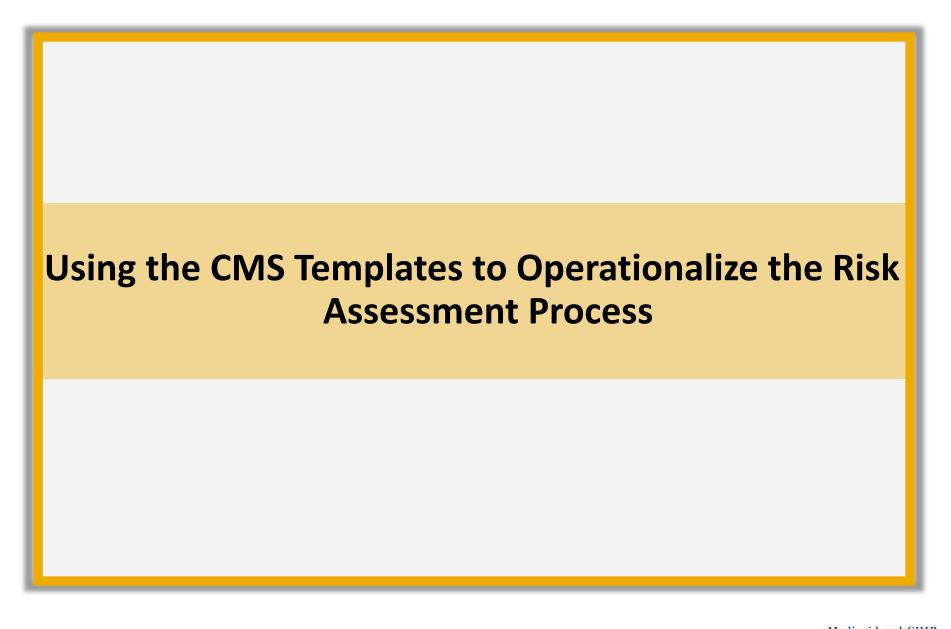
5. Document the program's risk profile

Involves documenting key findings and conclusions from previous risk assessment stages, including internal and external risks, perceived likelihood and impact, and prioritization of risks.

Elements of a Risk Profile

- Risks and vulnerabilities
- ✓ Risk owner
- Inherent and residual risk likelihood and impact
- ✓ Risk significance/score
- Existing controls
- ✓ Prioritization of risks
- ✓ Residual risk response/mitigation strategies including estimated go-live date







Step 1. Identify Flexibilities and/or Waivers

Identify eligibility flexibilities/waivers and their policy source

- First, collect all the eligibility-related flexibilities and waivers your state has implemented to manage the PHE, including new federal requirements, and assign an appropriate waiver/flexibility category.
- Then identify policy sources used to obtain these COVID-19 flexibilities and waivers (e.g., Medicaid and CHIP State Plan Amendments, Section 1135 Waivers).
 - This step is important because each one may have a different end date.

Waiver #	Waiver/Flexibility/Requirement Implemented by State	Waiver/Flexibility/Requirement Category	Policy Source(s) ³	Relevant Federal Regulations ⁴
1	EXAMPLE: As a condition of receiving the increased 6.2 federal medical assistance percentage (FMAP) under the Families First Coronavirus Response Act (FFCRA) through the end of the month in which the PHE ends, states may not terminate coverage for validly enrolled individuals found ineligible based on a redetermination of eligibility at renewal (unless the beneficiary requests a voluntary termination of eligibility, or the state determines that the individual is no longer considered to be a resident of the state).	EXAMPLE: Beneficiary Eligibility	EXAMPLE: Section 6008(b)(3) of the Families First Coronavirus Response Act	EXAMPLE: • 42 C.F.R. § 435.916: Periodic Renewal of Medicaid Eligibility



Step 1. Identify Flexibilities and/or Waivers, cont.

Identify eligibility flexibilities/waivers and their policy source

- Reference relevant federal regulations impacted by the COVID-19 PHE related policies.
 - This will help reorient stakeholders to the policies and/or procedures they must comply with as they plan to retire COVID-19 related policies.
 - Relevant federal regulations and other authorities for disaster-related flexibilities may be found in the Medicaid and CHIP Disaster Response Toolkit, Inventory of Medicaid and CHIP Flexibilities and Authorities in the Event of a Disaster, available at https://www.medicaid.gov/resources-for-states/disaster-response-toolkit/index.html

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Step 2. Identify Inherent Risks Template

Involves identifying and documenting all potential program risks, related to the waivers and flexibilities identified in Step 1, and key characteristics of these risks.

Table 2. I	Table 2. Identify Inherent Risks								
Risk#	Description of Inherent Risk (Associated Waiver/Flexibility/Requirement Number[s])	Category of Risk	Primary Source(s) of Risk						
			Policy	Processes	Operations				
1	EXAMPLE: Ineligible individuals remain enrolled in coverage after the permissible period (i.e., through the end of the unwinding period after the PHE ends) given the volume of cases to process and limited time to do so (1).	EXAMPLE: Improper continued enrollment	Х	Х	Х				
2	EXAMPLE: Higher likelihood of eligibility errors, including a risk of erroneous terminations, because of the increased workload associated with re-determining eligibility for many beneficiaries on a compressed time frame (1).	EXAMPLE: Receipt of category of services for which beneficiary is not eligible EXAMPLE: Denied access to services for which a beneficiary should be eligible	Х	Х	Х				



Step 3. Assess Risk Level

- Involves assessing each identified risk and assigning a risk score for the following categories (i.e., likelihood, beneficiary harm, dollars). Then individual risk scores are assessed and used to determine an overall risk score for each inherent risk.
- Risk scores can be qualitative, using low/medium/high; or quantitative, using a numeric scale (e.g., 5-point scale).

Table	Table 3. Identify Potential Outcomes and Assess Inherent Risks								
Risk #	Description of Inherent Risk (Associated Waiver/Flexibility/Requirement Number[s])	Potential Outcomes	Inherent Risk Scoring						
			Likelihood	Harm	Dollars	Overall			
1	EXAMPLE: Ineligible individuals remain enrolled in coverage after the permissible period (i.e., through the end of the unwinding period after the PHE ends) given the volume of cases to process and limited time to do so (1).	Improper continued enrollment, if state does not appropriately or timely redetermine eligibility based on identified changes based on change of circumstances or renewal Potential adverse audit finding	Medium	Low	Medium	Medium			
2									



Step 4. Determine Risk Tolerance

- Eliminating all risk is not a realistic goal. Effective managers define and document their level of tolerable risk.
- When faced with limited time and/or resources, States should prioritize those risks with higher risk scores.
- Management should revise risk tolerances as needed to ensure they are consistent with all program requirements and expectations.

Risk #	Description of Inherent Risk (Associated Waiver/Flexibility/Requirement Number[s])	Description of Inherent Risk (Associated Potential Outcomes Inherent Risk Scoring siver/Flexibility/Requirement Number[s])					Risk Tolerance
			Likelihood	Harm	Dollars	Overall	
1	EXAMPLE: Ineligible individuals remain enrolled in coverage after the permissible period (i.e., through the end of the unwinding period after the PHE ends) given the volume of cases to process and limited time to do so (1).	Improper continued enrollment, if state does not appropriately or timely redetermine eligibility based on identified changes based on change of circumstances or renewal Potential adverse audit finding	Medium	Low	Medium	Medium	Low



Step 5. Examine Existing Controls and Determine Risk Response

- After inherent risks are identified, compare them to existing controls to determine remaining (i.e., residual) risk level. This step can be completed in two stages:
 - First, determine what risk control activities (e.g., "existing controls"), if any, are currently in place that in some way mitigate each inherent risk.
 - Second, assess how successfully the existing controls are working: that is, how much risk remains despite the existing controls. The state then assigns a residual risk level score based on that assessment.
- For each residual risk, determine the following:
 - **Risk prioritization**: priority level (e.g., ranking).
 - Risk mitigation strategies: potential actions to mitigate residual risks.
 - Responsible entity: assigned owners, either individuals or divisions, assigned to manage implementation of mitigation strategies.
 - Estimated go-live date: proposed date of implementation of mitigation strategies.



Step 5.1. Compare Inherent Risks to Existing Controls to Determine Residual Risks and Determine Risk Response

Table	5. Examine Existing Controls and Determine/Pr	ioritize Resid	lual Risks			
Risk #	Description of Inherent Risk (Associated Waiver/Flexibility/Requirement Number[s])	Overall Score	Risk Tolerance	Existing Controls	Residual Risk Level	Risk Prioritization
1	EXAMPLE: Ineligible individuals remain enrolled in coverage after the permissible period (i.e., through the end of the unwinding period after the PHE ends) given the volume of cases to process and limited time to do so (1).	Medium	Low	Eligibility determination offices are pulling reports to identify cases with changes reported by beneficiaries. Eligibility determination offices are running reports to identify cases with upcoming and past due renewals during the PHE. State is processing all redeterminations that can be completed with available information, before the end of the PHE, to reduce the volume of work post-PHE. State is sending request for information to renewals that cannot be confirmed with ex parte information before the end of the PHE to reduce the volume of work post-PHE.	Medium	High
2						



Step 5.2. Determine Mitigation Strategies, Assign Owners, and Identify Go-Live Date

Risk #	Description of Inherent Risk (Associated Waiver/Flexibility/Requirement Number[s])	Overall Score	Risk Tolerance	Residual Risk Level	Mitigation Strategies	Responsible Entity	Estimated Go-Live Date
1	EXAMPLE: Ineligible individuals remain enrolled in	Medium	Low	Medium	EXAMPLE: 1.1 Avoidance:	EXAMPLE:	EXAMPLE:
	coverage after the permissible period (i.e., through the end of the unwinding period after the PHE ends) given the volume of cases to process and limited time to do so (1).				 To the extent permissible during the PHE, act on changes in circumstances and process renewals based on available information; 	Relevant agency component (or person within component)	06/15/2021
					Structure workforce tasks to focus on difficult cases that require manual review;	Relevant agency component (or person within component)	06/15/2021
					If the state has sufficient information to renew eligibility when redetermining eligibility based on a change, complete the renewal and provide the beneficiary with a new 12-month (or other) eligibility period.	Relevant agency component (or person within component)	06/15/2021



Step 6. Document Risk Profile

- Risk profile is the summation of findings and determinations from all previous steps.
- Final format of risk profile may vary.



Additional Considerations

Consider operational impacts when implementing mitigation strategies

- PI concerns may be balanced with efforts to ensure beneficiary access to care and mitigate coverage loss at the end of the PHE.
- Operational, process, and policy changes may be required to support mitigations.
 Mitigation policies need to be developed and eligibility workers need to be trained.
- States may need to consider time and resources when deciding on mitigation strategies.
- States may also determine whether and how frequently it will revisit the risk assessment process with respect to each program area to ensure that mitigation strategies are still effective and to make necessary adjustments.



- The following materials discussed during today's webinar are published on Medicaid.gov¹:
 - Risk Assessment Tool for Evaluating COVID-19 Flexibilities and Waivers Slide Deck
 - Risk Assessment Template and Step-by-Step Guide (in Word)
 - Risk Assessment Template (in Excel)



¹ https://www.medicaid.gov/resources-for-states/mac-learning-collaboratives/expanding-coverage-under-medicaid-and-chip/index.html





Appendix A: Implementation Example - CPI's COVID-19 PHE Risk Assessment Process



Application of the GAO Fraud Risk Management Framework

Case Example – CPI's COVID-19 PHE Risk Assessment

Risk Assessment Step	CPI's Application
Identify inherent risks affecting the program	 Identified and documented all COVID-19 PHE waivers and flexibilities as well as associated vulnerabilities in a risk assessment dashboard Categorized each flexibility into a broader topic area (e.g., beneficiary eligibility, FMAP) Contractors and CPI staff reviewed and updated dashboard weekly
2. Assess the impact of inherent risk	 Identified potential impact for all waivers/flexibilities (e.g., financial, patient harm) For each identified vulnerability, determined risk score for three risk categories (dollars, likelihood, harm) and averaged to assign overall risk score



Application of the GAO Fraud Risk Management Framework

Case Example – CPI's COVID-19 PHE Risk Assessment

Risk Assessment Step	CPI's Application
3. Examine existing controls and prioritize residual risks	 Identified potential mitigation strategies Assigned leads responsible for implementing mitigations and determined estimated go-live date (EGD) Presented risk assessment dashboard to leadership and key stakeholders to gather input and refine
4. Document risk profile	 Documented vulnerabilities and mitigation strategies in a risk assessment dashboard Contractors and CPI staff reviewed and updated dashboard weekly

*Note that CPI modified the GAO process slightly during their application and did not engage fully in the risk tolerance step. Thus this step has been omitted from this table resulting in slightly different numbering of the risk assessment steps than on the previous template slides.



Application of the GAO Fraud Risk Management Framework

Excerpt from CPI's COVID-19 PHE Risk Assessment Dashboard

Vulnerabilities	Risk Level				Mitigation Strategies
	Dollars	Likelihood	Harm	Overall	
States inappropriately terminate beneficiaries during the period in which the state is receiving enhanced FMAP, making the states ineligible for enhanced FMAP (1)	High	Medium	Medium	Medium	 Provide guidance to states regarding how to code these findings during their MEQC reviews



Appendix B: Additional Potential Risk Assessment Areas Impacted by COVID-19 Policies and Risk Assessment Considerations



Routine Program Integrity Safeguards

During the PHE, states should still have in place basic program integrity safeguards. As such, CMS encourages states to:

- Confirm that resources have been committed to your state's Surveillance and Utilization Review function, and that appropriate resources are in place to conduct preliminary investigations as required by 42 C.F.R. § 455.14.
- Utilize administrative actions, such as payment suspensions in cases of credible allegations of fraud, as outlined in 42 C.F.R. § 455.23.
- Ensure regular communication with your state's Medicaid Fraud Control Unit, and, where appropriate, other local, state, or federal law enforcement organizations, to discuss emerging trends related to COVID-19 and, as appropriate, to fast-track fraud referrals.
- Analyze fraud complaints to detect emerging trends.
- Work with CMS's Unified Program Integrity Contractors (UPICs) to perform data analyses, conduct investigations, and take appropriate administrative actions or make referrals to law enforcement when appropriate.



Routine Program Integrity Safeguards Cont'd

- Examine the medical necessity for items and services that would normally have required prior authorization but did not due to the PHE. We encourage states to prioritize the review of items and services provided to beneficiaries that were not approved through prior authorization before the COVID-19 PHE began and did not undergo prior authorization during the COVID-19 PHE (e.g., the item or service was provided for the first time during the PHE without undergoing prior authorization).
- Fully implement the six National Correct Coding Initiative methodologies pursuant to the requirements of section 1903(r) of the Act.
- Develop measures to ensure that a state will remove temporarily enrolled providers from their programs, or fully screen and enroll them, within the permissible time-period after the PHE ends.
- Participate with CMS and other states in regular technical assistance group calls that help share best practices and provide guidance to states on provider enrollment activities during the PHE.



Telehealth

When analyzing telehealth services, CMS encourages states to consider the below list of program integrity questions, which includes, but is not limited to the following:

- Does the state have clear, effective policies in place to ensure program integrity when telehealth is used?
- How has the state avoided paying for services provided by telehealth that are not covered?
- How has the state ensured that services provided by telehealth requiring audio and video are not delivered via audio only?
- What measures has the state taken to set up services provided by telehealth for individuals who have limited access to Internet, broadband, or smartphones in a way that implements anti-fraud mechanisms?
- How has the state ensured that billed services provided by telehealth were actually rendered and medically necessary?



Telehealth Cont'd

- How has the state ensured that providers are not fraudulently billing for services provided via telehealth, especially for beneficiaries with whom the providers have no prior relationship?
- Are Medicaid Management Information System edits in place to monitor for such things as "impossible days" where providers bill for more services than is reasonable or possible to perform in a single day, or the ordering of unnecessary items or services?
- Has the state engaged managed care plans (MCPs) to ensure the MCPs have processes and procedures in place to identify and investigate fraud, waste, and abuse for services provided by telehealth?
- How has the state educated providers about rapidly changing telehealth requirements?
- How has the state identified services billed incorrectly because of provider confusion about telehealth requirements?
- How has the state engaged with CMS, its Medicaid Fraud Control Unit, and other federal and state partners to ensure proper program integrity safeguards are in place for services provided by telehealth?



Managed Care

When analyzing managed care contracts, CMS encourages states to consider the below list of program integrity questions, which includes, but is not limited to the following:

- How has the state monitored capitation rates to ensure that such rates are set appropriately and in accordance with actuarial soundness requirements, given the uncertainties of the COVID-19 PHE?
- In states that have increased capitation rates as a result of the pandemic, has the state put additional monitoring in place to ensure that beneficiaries are assigned to the correct rate cell?
- How has the state monitored and verified the results of risk mitigation strategies used for managed care contract payments?



Managed Care Cont'd

- Has the state ensured that its MCPs have processes and procedures in place to identify, investigate, and refer potential fraud related to COVID-19 to the state's Program Integrity Unit, Medicaid Fraud Control Unit, or other law enforcement official?
- Has the state been meeting with its MCPs to discuss specific cases and emerging trends related to COVID-19 fraud, waste, and abuse? If yes, how frequently does the state plan to hold such meetings?
- How has the state confirmed that state directed payments are being used to increase payments for actual utilization of services in compliance with 42 C.F.R. § 438.6(c) and as specified in the contract?



COVID-19 Testing

When analyzing the COVID-19 Testing benefits and services, CMS encourages states to consider the below list of program integrity questions, which includes, but is not limited to the following:

- How can a state demonstrate that, for individuals enrolled in the COVID-19 testing group, it restricts services to only COVID-19 testing, testing-related services, and COVID-19 related treatments?
- How can states ensure the testing and testing-related services are given to the appropriate beneficiaries?
- How are states ensuring that Medicaid beneficiaries in institutional settings such as nursing facilities and institutions for mental diseases are getting tested?
- What mechanisms are in place to ensure that a state covers testing services and treatments for COVID-19, including vaccines, specialized equipment and therapies with no cost sharing during the period in which the state is receiving the temporarily increased FMAP under section 6008 of the FFCRA?



Premiums, Cost-Sharing, and Payments

When analyzing changes to premiums, cost-sharing, and payments, CMS encourages states to consider the below list of program integrity questions, which includes, but is not limited to the following:

- What mechanisms are in place to ensure that a state does not increase premiums during the period in which the state is receiving temporarily increased FMAP under section 6008 of the FFCRA?
- What safeguards does the state have in place to oversee interim payments resulting in providers receiving additional funds that are never reconciled and/or interim payments in excess of actual claims never being returned to the state?



Home Health and HCBS

When analyzing Home Health and Home and Community Based Services, CMS encourages states to consider the below list of program integrity questions, which includes, but is not limited to the following:

- What measures does the state have to detect providers who order home health services for beneficiaries who do not meet requirements?
- To what extent are communication systems between the state and Medicaid providers effective in communicating critical information, (e.g. emergency measures, temporary flexibilities), during a PHE?
- What measures does the state have to identify HCBS providers, including family caregivers, who are paid for providing services that are not actually provided?



Home Health and HCBS Cont'd

- What measures does the state have to re-assess eligibility for HCBS for beneficiaries temporarily covered under PHE flexibilities after the PHE ends?
- What program integrity measures does the state have in place for new and adjusted HCBS benefits, such as services that were temporarily added, temporarily allowed payment for services rendered by family caregivers or legally responsible individuals, and temporarily increased payment rates?
- What safeguards are in place to ensure HCBS retainer payments are made in accordance with the provisions outlined in the June 30, 2020 FAQs?¹



Monitoring, Oversight, and Education

When analyzing monitoring and oversight mechanisms, CMS encourages states to consider the below list of program integrity questions, which includes, but is not limited to the following:

- What measures does the state have to detect billing for lab tests, including add-on and panel testing, and other services that may not be medically necessary based on the beneficiary's condition or state policy?
- What measures does the state have to detect scammers who provide fake COVID-19 tests or other non-related items and services for the purpose of collecting beneficiary personally identifiable information and defrauding the Medicaid program?
- What measures does the state have to monitor utilization related to payment changes during the PHE that may indicate an increased risk of fraud, waste, and abuse?
- What measures has the state taken to educate beneficiaries about potential fraud schemes such as not sharing their Medicaid card or number with anyone except a Medicaid provider?

