

First Tier, Downstream and Related Entities (FDR) Medicare Compliance Program Guide

June 2022

I. Introduction – CHRISTUS Health Plan’s Medicare Compliance Program

CHRISTUS Health Plan (CHP) is committed to maintaining a work environment that promotes our Mission, Core Values, and regulatory compliance with state and federal laws. Such an environment can exist only if CHRISTUS Associates and Health Care Partners (e.g. physicians, other health professionals, volunteers, vendors, contractors, subcontractors, suppliers and agents) strive to fulfill the Mission and work in accordance with the CHP Core Values in performing daily tasks.

CHP’s Medicare compliance program helps to serve our members ethically

We’re committed to practicing business in an ethical manner. Our Medicare compliance program helps us to:

- Reduce or eliminate fraud, waste and abuse (FWA);
- Identify any potential non-compliance, and report it within the appropriate channels;
- Ensure we comply with applicable state, federal and accreditation laws, rules and regulations; and
- Reinforce our commitment to compliance

CHP uses external entities to bring members cost-effective health care solutions

CHP offers Medicare Advantage (MA) plans. We contract with external entities and individuals as a cost-effective and efficient way of providing administrative and health care services on our behalf. Some of the services provided by external entities are services that we are required to perform under our contract with the Centers for Medicare & Medicaid Services (CMS). CMS refers to these entities as First Tier, Downstream and Related Entities (FDRs).

You will find specific requirements in this document

CMS also requires that CHP’s FDRs fulfill specific CHP Medicare compliance program requirements in this document. The Code of Federal Regulations (CFR) outlines these requirements, and they are defined by CMS in the January 11, 2013, Compliance Program Guidelines in Chapter 21 of the [Medicare Managed Care Manual](#) and Chapter 9 of the [Prescription Drug Benefit Manual](#).

The importance of following requirements

You received this guide because we’ve identified you as a First Tier Entity. This means that you must comply with these requirements.

II. What is an FDR?

CHP uses the current CMS definitions to define First Tier, Downstream and Related Entities:

First Tier Entity is any party that enters into a written arrangement, acceptable to CMS, with an MA organization or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare-eligible individual under the MA program or Part D program. (See 42 CFR § 422.500 and 423.501.)

Downstream Entity is any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit or Part D benefit, below the level of the arrangement between an MA organization or applicant or a Part D plan sponsor or applicant and a First Tier Entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services. (See 42 CFR § 422.500 and 423.501.)

Related Entity means any entity that is related to an MA organization or Part D sponsor by common ownership or control and:

- Performs some of the MA organization or Part D plan sponsor's management functions under contract or delegation;
- Furnishes services to Medicare enrollees under an oral or written agreement;
- Leases real property or sells materials to the MA organization or Part D plan sponsor at a cost of more than \$2,500 during a contract period (See 42 CFR § 422.500 and 423.501.)

FDRs providing health care services

The CHP Medicare compliance program requirements described in this guide apply to health care providers contracted with CHP to participate in our Medicare network. This includes physicians, hospitals, and other provider types. Here are the reasons why:

- MA regulations and CMS rules state that providers contracted with CHP to provide health care services to our Medicare members are "First Tier Entities."
- Chapter 21 of the manual lists "health care services" as an example of the types of functions that a third party can perform that relate to an MA organization's contract with CMS. This would give third parties "First Tier Entity" status. (See last bullet point in the manual, Chapter 21 § 40.) So these requirements apply to providers that actually deliver health care services to our Medicare members.
- CMS provides a chart in the manual, Chapter 21 § 40, showing that entities providing health services and hospital groups are First Tier Entities. If CHP contracts with a hospital group and don't have a direct contract with the group's hospitals and other providers, the hospitals and providers are Downstream Entities. This means that the hospital group is a First Tier Entity and must comply. It also must make sure its Downstream Entities comply with the CMS compliance program requirements in this guide.

FDRs providing administrative services

The CHP Medicare compliance program requirements also apply to entities that the Health Plan contracts to perform administrative service functions relating to MA or Part D contracts with CMS. Some examples of administrative service functions include:

- Claims processing;
- Patient management; and
- Credentialing*

Other examples of FDRs include delegates, agents, broker organizations, pharmacies and other individuals, entities, vendors or suppliers contracted with CHP to provide administrative and/or health care services for our Medicare plans. You can find more information in the manual, Chapter 21 § 40, including the Stakeholder Relationship Charts.

**Under CHP's MA contract with CMS, we're required to credential health care providers that participate in our Medicare network. We may contract with entities to perform these credentialing services on our behalf under a delegation agreement. CMS considers these delegated credentialing entities to be First Tier Entities. CMS identifies delegated entities as First Tier Entities in the manual, Chapter 11§ 100.5.*

III. FDR Medicare compliance program and attestation requirements

It's important that CHP FDRs are in compliance with applicable laws, rules and regulations. Although we contract with FDRs to provide administrative and/or health care services for our Medicare plans, it is CHP's responsibility to fulfill the terms and conditions of the contract with CMS and meeting applicable Medicare program requirements. The FDRs are responsible for complying with relevant CHP Medicare compliance program requirements. FDRs must also ensure that their Downstream Entities, which they use for our CHP MA plans, also comply with applicable laws and regulations, including the requirements in this guide.

Compliance Program Requirements

Your organization and all of your Downstream Entities must comply with CHP Medicare compliance program requirements, which is summarized in this guide. Please review to ensure that you have internal processes to support your compliance with these requirements each calendar year. These requirements include, but are not limited to:

- Effective January 1, 2016, completion of the CMS *Combating Medicare Parts C and D Fraud, Waste, and Abuse Training* and the CMS *Medicare Parts C and D General Compliance Training* modules annually, and within 90 days for a new hire;
- Code of conduct/compliance program policy distribution annually, and at 90 days for a new hire;
- OIG/GSA Exclusion List screenings monthly;
- Reporting FWA and compliance concerns to CHP upon identification;
- Offshore operations and CMS reporting;

- Specific federal and state compliance obligations;
- Monitoring and auditing of First Tier, Downstream and Related Entities

For tools that may help you meet these requirements, please see “Toolbox of resources for FDRs” at the end of this guide.

What may happen if you don’t comply with CMS Medicare Requirements?

If our FDRs fail to meet CMS Medicare compliance program requirements, it may lead to:

- Development of a corrective action plan (CAP) based on the identified gap;
- Retraining; and/or
- Termination of your contract and relationship with CHP

CHP’s actions in response to noncompliance will depend on the severity of the compliance issue. If an FDR identifies areas of noncompliance (for example, refusal of an employee to complete the required FWA training), they must take prompt action to remediate the issue and prevent recurrence.

Attestation requirements

You must maintain evidence of your compliance with these Medicare requirements (for example, employee training records and CMS certificates of FWA training completion) for no less than 10 years. Also, annually, an authorized representative from your organization must attest to your compliance with the CHP Medicare compliance program requirements described in this guide. An authorized representative must be an individual who has responsibility directly or indirectly for all:

- Employees;
- Contracted, temporary, or volunteer personnel;
- Providers/practitioners;
- Vendors who provide health care and/or administrative services for CHP MA plans.

This could be your Compliance Officer, Chief Medical Officer, Executive Officer or similar positions.

Key Reminders;

- You may be asked to provide evidence of compliance at any time
- In addition to completing an attestation, CHP and/or CMS may request that you provide material evidence of your compliance for monitoring/auditing purposes
- If you have questions or concerns regarding the Medicare Compliance Program requirements, you may contact CHPVendorRelations@christushealth.org

Please continue reading for a description of each Medicare compliance program requirement.

A. Fraud, waste and abuse (FWA) training and general compliance training

FWA and general compliance training

As an FDR, you must ensure that your applicable employees and Downstream Entities complete fraud, waste and abuse and general compliance training annually, and within 90 days of a new hire. Effective January 1, 2016, you/your organization must ensure their completion of the CMS [Combating Medicare Parts C and D Fraud, Waste, and Abuse Training](#) module, as well as the CMS <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MedCandDGenCompdownload.pdf> module. CMS may update these required training modules annually.

Your applicable employees and Downstream Entities assigned to provide administrative and/or health care services for CHP Medicare plans can access these trainings in one of three ways:

- Complete the modules on the [CMS Medicare Learning network \(MLN\)](#) website. The general compliance course is titled *Medicare Parts C and D General Compliance Training*, and the FWA training is titled *Combating Medicare Parts C and D Fraud, Waste, and Abuse Training*. Once completed, download and retain the certificate of completion. The certificates must be made available to CHP and/or CMS upon request.
- Your organization may also download or print content of the CMS training modules from the MLN website to incorporate into your training materials/system. The content of the CMS training modules **cannot** be changed to ensure the integrity and completeness of the training. You/Your organization must retain records of completion which must be made available to CHP and/or CMS if requested.
- Your organization can incorporate the content of the CMS training modules from the MLN website into written documents for providers (for example, provider guides or participation manuals).

Training requirements

Regardless of the method used, the training must be completed:

- Within 90 days of initial hire or the effective date of contracting; and
- At least annually during each calendar year (January 1 – December 31) thereafter.

We request that you confirm your compliance with these requirements as part of CHP's annual attestation process. However, you must also maintain evidence of training completion. Evidence of completion may be in the form of certificates, attestations, training logs or other means determined by you to best represent fulfillment of your obligations. If you use training logs or reports as evidence of completion, they must include: (i) Employee Names; (ii) Dates of Employment; (iii) Dates of completion; and (iv) Passing scores (if captured).

Who should complete training?

Not every employee is required to complete training. Below are examples of critical roles within an FDR that should be required to fulfill the training requirements:

- Senior administrators or managers directly responsible for the FDR’s contract with CHP (for example, senior vice president, departmental managers, chief medical or pharmacy officer);
- Individuals directly involved with establishing and administering CHP’s formulary and/or medical benefits coverage policies and procedures;
- Individuals involved with decision-making authority on behalf of CHP (for example, clinical decisions, coverage determinations, appeals and grievances, enrollment/disenrollment functions, processing of pharmacy or medical claims);
- Reviewers of beneficiary claims and services submitted for payment;
- Individuals with job functions that place the FDR in a position to commit significant noncompliance with CMS program requirements or health care FWA.

Please refer to the CHP website link, <https://www.christushealthplan.org/provider-resources/compliance>, if you are unsure which employees at your organization should take the training. If you still have questions, you can email CHPVendorRelations@christushealth.org for assistance.

The only exception to the training requirement is if you/your organization is “deemed” to have met the FWA certification requirements through enrollment into Medicare Part A or B of the Medicare program or through accreditation as a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). Parties deemed to have met the FWA training through enrollment into the CMS Medicare program, must still complete the General Compliance Training.

For training requirements and information about deemed status see: 42 CFR § 422.503 (b)(4)(vi)(C) for MA, 42 CFR § 423.504 (b)(4)(vi)(C) for Part D, and Manual, Chapter 21 § 50.3

B. Code of conduct/compliance program policy distribution

You must provide your employees with your standards of conduct

FDRs must provide either [CHRISTUS Health’s Code of Ethics](#) and Medicare compliance policies (available upon request by emailing CHPCompliance@christushealth.org, or your own comparable code of conduct/compliance policies (collectively, “standards of conduct”) to all applicable employees and Downstream Entities who provide administrative and/or health care services for our Medicare plans. CHP’s compliance policies can be located on the CHP website at <https://www.christushealthplan.org/member-resources/forms-documents/medicare>. The written compliance policies and standards of conduct must contain all of the elements set forth in Section 50.1 and its subsections of Manual, Chapter 21, and articulate the entity’s commitment to comply with federal and state laws, ethical behavior and compliance program operations. You must distribute standards of conduct/policies:

- Within 90 days of hire or the effective date of contracting;
- When there are updates to the standards of conduct, or major policy and procedure changes;
- Annually thereafter

Evidence of your distribution of the standards of conduct must be retained. You can find the standards of conduct requirements in:

- 42 CFR § 422.503 (b)(4)(vi)(A) for MA
- 42 CFR § 423.504 (b)(4)(vi)(A) for Part D
- Manual, Chapter 21 § 50.1

C. Exclusion list and Preclusion list screenings

Exclusion List

Federal law prohibits Medicare, Medicaid and other federal health care programs from paying for items or services provided by a person or entity excluded from participation in these federal programs. Therefore, before hiring or contracting, and monthly thereafter, each FDR must check exclusion lists from the Office of Inspector General (OIG) and the U.S. General Services Administration (GSA). This is to confirm that employees and Downstream Entities performing administrative and/or health care services for CHP's Medicare Plans aren't excluded from participating in federally funded health care programs. You can use these two websites to perform the required exclusion list screening:

- **OIG List of Excluded Individuals and Entities (LEIE)**
- **GSA's System for Award Management (SAM)**

Also, FDRs must maintain evidence of checking the exclusion lists. Acceptable documentation or evidence may be tracking logs or other records showing completion of screening each employee and Downstream Entity in accordance with current laws, regulations and CMS requirements. Be sure to retain evidence of the screening that was conducted including date of occurrence, the results of the screening and any actions taken if sanctioned individuals or entities were identified. CHP may do a random audit of screenings at any point in time to ensure regulatory compliance with the above.

CHP is also required to check exclusion lists before hiring or contracting with any new employee, temporary employee, volunteer, consultant, governing body member or FDR, and monthly thereafter. CHP cannot check these exclusion lists for your employees and Downstream Entities.

You must take action if an employee or Downstream Entity is on the exclusion list.

If any of your employees or Downstream Entities are on one of these exclusion lists, you must immediately remove them from any work directly or indirectly related to CHP's Medicare plans and notify CHP immediately.

Exclusion list requirements are noted in § 1862(e)(1)(B) of the Social Security Act, 42 CFR §§ 422.503(b)(4)(vi)(F), 422.752(a)(8), 423.504(b)(4)(vi)(F), 423.752(a)(6), 1001.1901, and further described in the manual, Chapter 21 § 50.6.8.

Preclusion List

The Centers for Medicare & Medicaid Services adopted the requirement that, in order for contracted and non-contracted providers to receive payment from a Medicare plans, such providers must not be included on the Preclusion List. Also, in order for Part D drugs to be covered by a Part D plan, the prescriber must not be included on the Preclusion List. CMS will provide one Preclusion List with monthly updates, thereafter. It is required that Medicare Plans and Part D plans must remove any contracted provider and any pharmacy within their network that is found on the preclusion list as soon as possible.

The Preclusion List consists of providers (individuals and entities) that fall within either of the following categories:

1. Are currently revoked from Medicare, are under an active reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program; or
2. Have engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program.

You can use the following websites to view the CMS Reference Guides. Both provide step-by-step instructions for accessing the list.

- [CMS Preclusion List Quick Reference Guide](#)
- [User Reference Guide for CMS Preclusion List](#)

You must take action if a contracted provider or pharmacy within your network is found on the preclusion list.

CHP expects FDRs to check the preclusion list on a monthly basis. FDRs must maintain evidence of checking the preclusion list and providing enrollee notification. CMS recommends that Medicare Plans and Part D Plans provide Medicare beneficiaries with at least 60 days' advance notice before denying payment for a healthcare service or item or rejecting a pharmacy claim. CHP expects FDRs to follow this recommendation. Acceptable documentation may include a tracking log or other records showing completion of a preclusion check. Also, it is mandatory to include evidence that notification was provided to CHP members within the recommended timeframe, if precluded providers or pharmacies were identified. CHP may do a random audit of the FDR's preclusion list check process at any point in time to ensure compliance with CMS requirements.

Additionally, if a provider or pharmacy is found on the OIG exclusion file, it is not required to check the preclusion list. Preclusion list requirements are noted in §§ 422.222 and 423.120(c) (6) of the CMS-4185 Final Rule, Federal Register.

D. Reporting FWA and compliance concerns to CHP

There are a number of ways to report suspected or detected noncompliance or potential FWA. Don't worry – your reports are confidential. You can find this information in CHP's reporting mechanism flyer, or at the following link; <https://www.christushealthplan.org/member-resources/fraud-and-abuse>. You can share the flyer with your employees or Downstream Entities. You can also keep it as a reference tool and use your own internal processes for reporting and collecting these issues. If you choose to use your own processes, make sure you report it to CHP. You can also refer back to our Code of Ethics for information on our reporting guidelines.

You must adopt and enforce a zero-tolerance policy for retaliation or intimidation against anyone who reports suspected misconduct.

CHP's Compliance Officer, Nicolle Mustafa, is based at our corporate offices in Irving, TX. Questions or concerns for Nicolle and/or her compliance subject matter experts can be sent to CHPCompliance@christushealth.org.

E. Offshore operations and CMS reporting

To help make sure we comply with applicable federal and state laws, rules and regulations, you are required to request permission to perform offshore services or to use an individual or entity (offshore entity) to perform services for CHP's Medicare plans when the individual or entity is physically located outside the United States or one of its territories (that is, American Samoa, Guam, Northern Marianas, Puerto Rico and Virgin Islands). The approval must come from an authorized CHP representative in advance and in writing for the use of such offshore individual or entity.

Notify the Health Plan immediately if you plan to use an offshore entity

If you perform services offshore or use an offshore entity to perform services involving the receipt, processing, transferring, handling, storing or accessing of Medicare member protected health information (PHI) and CHP has approved the arrangement, CHP is required to submit an attestation to CMS. Therefore, you must immediately notify your CHP relationship manager if you engage in offshore services yourself or through an offshore entity.

One example provided by CMS of offshore services that trigger this attestation requirement is "offshore subcontractors that receive radiological images for reading because beneficiary personal health information (PHI) is included with the radiological image and the diagnosis is transmitted back to the U.S."

F. Specific federal and state compliance obligations

Based on the services that you/your organization perform for CHP's Medicare plans, you may be subject to other federal and state laws, rules and regulations that aren't described in this guide. If you have questions about the Medicare requirements for the services that you/your organization perform, consult with your CHP Relationship Manager. CHP expects that you/your organization demonstrate compliance with all applicable federal and state laws, rules and regulations.

G. Monitoring and Auditing of First Tier and Downstream Entities

CMS requires organizations such as CHP to develop a strategy to monitor and audit our First Tier Entities. This helps ensure that our First Tier Entities comply with all applicable laws and regulations and that our First Tier Entities must monitor the compliance of their Downstream Entities. Therefore, if you choose to subcontract with other individuals/parties to provide administrative and/or health care services for CHP's Medicare plans, you must make sure that these Downstream Entities abide by all laws and regulations that apply to you as a First Tier Entity. This includes ensuring:

- Contractual agreements contain all CMS-required provisions
- They comply with the Medicare compliance program requirements described in this guide
- They comply with any applicable Medicare operational requirements

Not every subcontractor is considered a Downstream Entity. Only those entities who provide administrative or health care services for CHP's Medicare Advantage and Prescription Drug Plan products may be Downstream Entities. Review the grid at <https://www.christushealthplan.org/provider-resources/compliance> to help you determine who is a Downstream Entity for your organization. If you have additional questions, feel free to contact us for assistance at CHPVendorRelations@christushealth.org.

Additionally, you/your organization must conduct sufficient oversight (that is, auditing and monitoring) to test and ensure that your employees and Downstream Entities are compliant. You must retain evidence of oversight completion, ensure root-cause analysis is conducted for any deficiencies, and implement corrective actions or take disciplinary actions such as contract termination, as necessary, to prevent recurrence of noncompliance.

Expect routine monitoring and audits

We routinely monitor and periodically audit our FDRs. This helps us ensure compliant administration of our contracts with CMS to offer Medicare plans, as well as applicable laws and regulations. Each FDR must cooperate and participate in these monitoring and auditing activities. If an FDR performs its own audits, we may ask for the audit results affecting CHP's Medicare business. Also, FDRs must routinely monitor and/or periodically audit their Downstream Entities if they are used for CHP's Medicare plans.

If we determine that an FDR is out of compliance with any of the requirements in this guide, a Corrective Action Plan (CAP) will need to be created. We can assist the FDR address the identified compliance issues.

These monitoring and auditing requirements are noted in:

- 42 CFR § 422.503(b)(4)(vi)(F) for MA
- 42 CFR § 423.504(b)(4)(vi)(F) for Part D
- Manual, Chapter 21 § 50.6.6

Questions or Concerns

For compliance questions or concerns, you can email us at CHPCompliance@christushealth.org.

For general FDR/Vendor questions or concerns, you can email us at CHPVendorRelations@christushealth.org.

Resources for FDRs

General compliance and FWA training	
CMS General Compliance Training	Organizations can use the CMS general compliance training module on the CMS Medicare Learning Network (MLN) . It can be completed on the MLN, after registration. It is titled <i>Medicare Parts C and D General Compliance Training</i> . Organizations can download it and incorporate the module, unmodified, into their existing training materials/systems.
CMS FWA Training	Organizations can use the CMS FWA training module on the MLN . It can be completed on the MLN, after registration. It is titled <i>Combating Medicare Parts C and D Fraud, Waste, and Abuse Training</i> . Organizations can download it and incorporate the module, unmodified, into their existing training materials/systems.
Proof of training completion	CMS requires FDRs to maintain evidence of training completion. FDRs must retain this evidence for 10 years. The CMS training completion certification is evidence of completion. Organizations may use a sample log to document employees' completion of training. Organization's Downstream Entities can also use this log to document their employees' training completion.
Code of conduct and compliance policies	
Which code should be used?	Organizations are encouraged to distribute CHRISTUS's Code of Ethics to employees.
Which Medicare compliance policies are applicable?	CHRISTUS's Code of Ethics in addition to specific Medicare policies, available upon request, detail the CHRISTUS Medicare compliance program.
What information should be provided to employees?	Organizations may use this announcement template to share CHRISTUS's Code of Ethics and compliance policies with employees and Downstream Entities.
Exclusion list screenings	
How is the OIG site accessed?	Organizations must complete OIG exclusion list screenings before hiring/contracting and monthly after that for your employees and Downstream Entities. Use this OIG/GSA screening log to aid in your process.
How is the GSA's SAM site accessed?	Organizations must complete the GSA's SAM exclusion list screenings before hiring/contracting and monthly after that for your employees and Downstream Entities. Use this OIG/GSA screening log to aid in your process.
Reporting mechanisms	
How is noncompliance or potential FWA reported to CHRISTUS?	Organizations must report suspected or detected noncompliance or potential FWA that impact CHRISTUS directly to CHRISTUS. The flyer for Reporting Fraud, Waste or Abuse in the CHRISTUS Health Care System should be shared throughout the organization so that employees know how to report concerns.
Monitoring and oversight	
Which subcontractors are Downstream Entities?	Not every subcontractor is a Downstream Entity. This grid has examples of Downstream Entities.
What type of oversight of Downstream Entities should be done?	Organizations must conduct oversight of your Downstream Entities. An FDR attestation may help your Downstream Entities self-assess and report the status of their compliance to you.
How will the organization know if it is in compliance with Medicare requirements?	Organizations can use this example tool to assess their compliance with the Medicare compliance program requirements. The organization can also modify the tool to assess compliance of Downstream Entities.
What is required regarding Offshore operations?	Organizations must request permission to use an offshore individual or entity to perform services that involve the processing, transferring, handling, storing or accessing of Medicare member PHI. Use this form to request permission and return the completed form to CHPVendorRelations@christushealth.org .

