

2019 Banner Health Network Annual Compliance Attestation and Disclosure Statement for Downstream Entities

Your Organization is receiving this “Annual Compliance Attestation and Disclosure Statement” because your Organization is contracted with Banner Health Network (BHN) to provide services as a Downstream Entity under a Medicare Advantage (MA) contract.

The Centers for Medicare & Medicaid Services (CMS) identifies certain contractors as First Tier, Downstream and Related Entities (FDRs). Those entities have obligations to minimize the inappropriate use of federal healthcare funds. BHN is contracted with several MA plans—under which BHN is considered a First Tier entity—and therefore is subject to those obligations. Under your contract with BHN, your Organization is considered a Downstream Entity to BHN, and therefore, CMS holds you subject to those obligations as well.

BHN is required to oversee that any Downstream Entity is in compliance with these obligations. BHN uses an Attestation which you will find accompanying this document as Attachment A. The Attestation must be completed and signed by an individual with oversight responsibility for your Organization’s contracted services or activities and who has the authority to sign on behalf of your Organization.

In addition, you will find two other documents. Attachment B is an Offshore Attestation to be used if you have offshore subcontractors and have not previously provided that information to BHN. Attachment C is a Downstream Entity Compliance Guide providing relevant compliance materials for your review and use as needed.

Attestation Form Submission Instructions

Please complete Attachment A: Compliance Attestation in its entirety and provide to BHN by December 31st of each year.

If you have already completed an attestation in 2019, you can disregard this notice.

The completed Attestation may be emailed to: BHNcompliance@bannerhealth.com.

BHN Compliance Contact Information:

- Teresa McMeans, Compliance Officer: Teresa.McMeans@bannerhealth.com / (602) 747-3140
- Robin Morrone, Senior Compliance Consultant: Robin.Morrone@bannerhealth.com / (602) 747-8454

ATTACHMENT A: Compliance Attestation

Directions: Please read the information below. Make your selections by checking the boxes. If “other” is selected, please include comments.

Code of Conduct

Please select one:

- My Organization adopts and complies with Banner Health’s Code of Conduct and distributes it to employees within 90 days of hire, upon revision, and annually thereafter; or
- My Organization has adopted another Code of Conduct that is materially similar to the Banner Health Code of Conduct that explains its commitment to comply with federal and state laws, ethical behavior, and compliance program operations. It is distributed to employees within 90 days of hire, upon revision, and annually thereafter. *(Please be prepared to provide copies if requested.)*
- Other / comments: _____

Compliance Program

- My Organization acknowledges it is required to meet all applicable federal healthcare statutes, regulations, and sub-regulatory guidance, and has a mechanism to assure its employees are aware of these requirements, i.e., training, testing, or other mechanisms.
- Other / comments: _____

Policies and Procedures

Please select one:

- My Organization has in place and is in compliance with policies and procedures to promptly respond to, resolve and report to BHN all identified compliance deficiencies in accordance with applicable laws, rules, and regulations including CMS regulatory/sub-regulatory guidance. The policies and procedures are distributed to employees within 90 days of hire, upon revision, and annually thereafter.
- Other / comments: _____

Reporting Mechanisms

Please select one:

- My Organization communicates to employees how to report suspected or detected non-compliance or potential fraud, waste, or abuse, and that it is their obligation to report without fear of retaliation or intimidation against anyone who reports in good faith. My organization either requests employees report concerns directly to BHN or maintains confidential and anonymous mechanisms for employees to report internally. In turn, we report these concerns to BHN, when applicable.

- Other / comments: _____

Exclusion List Screening

Please select one:

- Prior to hire or start date and monthly thereafter, my Organization performs the required exclusion screening to confirm that employees, leaders, board members, contractors, vendors, and volunteers are not excluded to participate in federally funded health care programs according to the HHS OIG and the GSA SAM.

- Other / comments: _____

Sub-Delegation Oversight

Please select one:

- My Organization currently does not subcontract or sub-delegate functions and/or activities to any third party. If my Organization engages in a subcontract or sub-delegate contract and/or agreement, we will obtain BHN’s prior written approval.

- My Organization does subcontract or sub-delegate functions and/or activities to third party(ies), and it has implemented an oversight program to assure compliance with all applicable laws, rules, and regulations including CMS regulatory/sub-regulatory guidance. Please provide list of any subcontracted or sub-delegated functions and/or activities.

- Other / comments: _____

HIPAA Privacy & Security

Please select one:

- My Organization has appropriate safeguards and controls in place to protect and secure BHN’s protected health information (PHI) from any intentional or unintentional use or disclosure, and has a process to notify BHN without reasonable delay and not later than 30 days from discovery of the breach if a breach of unsecured PHI occurs.

- Other / comments: _____

Payment Card Industry Data Security Standard

Please select one:

- My Organization accepts, stores, processes, or transmits payment card (credit/debit card) account data on behalf of BHN and is in compliance with the Payment Card Industry Data Security Standard (<https://www.pcisecuritystandards.org/>).

- My Organization does not accept, store, process, or transmit payment card (credit/debit card) account data on behalf of BHN.

Offshore Activities Reporting

Does your Organization have contractual relationships or functions located offshore? (Note: “Offshore” refers to any country not one of the fifty Unites States or one of the United States territories (American Samoa, Guam, Northern Marianas, Puerto Rico, and U.S. Virgin Islands.)

Yes **No**

If you checked yes, the Organization is required to complete Attachment B: Offshore Attestation providing additional details of each offshore arrangement, including protection of PHI.

ATTACHMENT A: Compliance Attestation

Organizational Information and Signature

Please note that this Attestation is intended to be completed at the contract level. If your Organization has multiple tax identification numbers (TINs) under one contract, please complete one form and list each TIN.

Organization Name		Date (xx/xx/xxxx)	
Compliance Contact Name & Title		Email Address	
Phone Number (xxx) xxx-xxxx	Fax Number (xxx) xxx-xxxx	NPI (10 digits)	
Tax Identification Number(s) (required) (9 digits)			
1.	6.	11.	16.
2.	7.	12.	17.
3.	8.	13.	18.
4.	9.	14.	19.
5.	10.	15.	20.

Authorized Representative Information:

Authorized Representative Name	Title
Email Address	Phone Number

I certify and attest that, as the authorized representative with responsibility directly or indirectly for all employees, providers/practitioners, contractors or vendors who provide administrative or health care services for Medicare Advantage enrollees under this contract, that the statements above are true and correct to the best of my knowledge.

My Organization agrees to maintain supporting documentation regarding the above statements for a period of at least ten (10) years plus the current contract year. Further, my Organization agrees to provide documentation or evidence to BHN in regard to the above responses upon request for monitoring and auditing purposes. My Organization understands that the inability to produce this evidence will result in a request from BHN for a Corrective Action Plan (CAP) or other contractual remedies such as contract termination.

Signature: _____

Date: _____

ATTACHMENT B: Offshore Attestation

Required Information

Company (Contractor) name:

Offshore Entity name (Company or its Downstream Entity):

Offshore Entity country:

Offshore Entity address:

Describe offshore functions being performed by the Offshore Entity (“Offshore Services”):

State the proposed or actual effective date for the aforementioned Offshore Services:

Description of all PHI that will be provided to the Offshore Entity:

Explain why providing PHI is necessary to accomplish the Offshore Services:

Please describe any and all alternatives considered to avoid providing PHI, and why each alternative was rejected:

Medicare Offshore Services Attestation

Offshore Entity name: _____

With respect to the Offshore Services provided by the above named Offshore Entity to Medicare beneficiaries, Organization certifies and attests that:

- (i) The Offshore arrangement requires the Offshore Entity to have policies and procedures in place to ensure that Organization's Medicare Plans' PHI remains secure;
- (ii) The Offshore arrangement prohibits the Offshore Entity's access to data not associated with the arrangement;
- (iii) Organization has policies and procedures in place that allow Organization to immediately terminate the Offshore Services upon discovery of a significant security breach if such services are provided by Organization's Downstream Entity; and if Organization is performing the Offshore Services, Organization recognizes and agrees that BHN has the right to immediately terminate the Offshore Services upon discovery of a significant security breach;
- (iv) If the Offshore Services are being provided by Organization's Downstream Entity, Organization's contract with the Offshore Entity includes all required Medicare Part C and D language (e.g., record retention requirements, compliance with all Medicare Part C and D requirements, etc.);
- (v) If the Offshore Services are being provided by Organization's Downstream Entity, Organization will conduct an annual audit/review of its relationship with the Offshore Entity;
- (vi) If the Offshore Services are being provided by Organization's Downstream Entity, the annual audit/review results are used by Organization to evaluate the continuation of its relationship with the Offshore Entity;
- (vii) If the Offshore Services are being provided by Organization's Downstream Entity, Organization agrees to share such audit results with CMS, or with BHN should CMS require or request BHN to produce such audit results directly; and
- (viii) If the Offshore Services are being provided by Organization's Downstream Entity, Organization shall provide such additional information about its arrangement with the Offshore Subcontractor to CMS or its authorized agents as required or requested by CMS, and shall provide such additional information to BHN directly should CMS require or request BHN to produce such additional information about Organization's Offshore Subcontractor.

[Signature on following page]

ATTACHMENT B: Offshore Attestation

I certify, as an authorized representative of my Organization, that the statements made above are true and correct to the best of my knowledge. Also, my Organization agrees to maintain documentation supporting the statements above. My Organization will produce evidence of the above to BHN or CMS upon request. My Organization understands that the inability to produce this evidence will result in a request from BHN for a Corrective Action Plan (CAP) or other contractual remedies such as contract termination.

Organization Name [Printed]

Signature of Organization's Authorized Representative

Date

Organization's Authorized Representative Printed Name and Title

Organization Mailing Address: _____

ATTACHMENT C: Downstream Entity Compliance Guide

Please note: This Guide is for informational purposes and does not constitute legal or compliance advice to the Organization. The Organization retains the obligation to seek such advice as needed.

I. INTRODUCTION

Banner Health Network (BHN) is committed to practicing business in an ethical manner. Our compliance program helps to:

- Reduce or eliminate fraud, waste, and abuse (FWA); and
- Make sure BHN and its contractors comply with applicable laws, rules, and regulations including CMS regulatory/sub-regulatory guidance.

A. Contractors/Vendors:

BHN has contracts to provide health care and administrative services with several Medicare Advantage (MA) plans. BHN then sub-contracts with several external individuals and entities as a cost-effective and efficient way of providing some of those services. The Centers for Medicare & Medicaid Services (CMS) refer to the various levels of contractors under MA contracts as First Tier, Downstream and Related Entities (FDRs). CMS requires that any of the compliance obligations that BHN (a First Tier Entity) has under its MA contracts flow down to any BHN contractor or vendor that meets the CMS definition of a Downstream or Related Entity.

B. Compliance Program Requirements:

These compliance program requirements are more fully explained in this document. They are outlined in the Code of Federal Regulations (C.F.R.), and CMS has provided further guidance in its Compliance Program Guidelines in Chapter 21 of the Medicare Managed Care Manual (MMCM) and Chapter 9 of the Prescription Drug Benefit Manual. (Note: These requirements are identical in these two sources.)

- Chapters 21 and 9 of the MCMM: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019326.html>

You have received this guide because BHN has identified you as a Downstream Entity. This means that you are required to comply with the CMS requirements.

II. WHAT IS AN FDR?¹

This acronym is “short hand” for three contracting parties—First Tier, Downstream and Related Entities—which are labeled, in essence, by how close their contract is to the MA plan.

A. CMS Definitions:

A *First Tier Entity* (such as BHN in this case) means any party that enters into an acceptable written arrangement with an MA Organization (or contract applicant) to provide administrative services or health care services for a Medicare-eligible individual.

A *Downstream Entity* (such as your Organization in this case) means any party that enters into an

¹ See 42 C.F.R. § 422.500.

acceptable written arrangement below the level of the arrangement between an MA Organization (or contract applicant) and a First Tier Entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

A *Related Entity* (probably not relevant in this case) means any entity that is *related to the MA Organization by common ownership or control* (emphasis added) and:

- (1) Performs some of the MA Organization's management functions under contract or delegation;
- (2) Furnishes services to Medicare enrollees under an oral or written agreement; or
- (3) Leases real property or sells materials to the MA Organization at a cost of more than \$2,500 during a contract period.

B. Types of Downstream Entities:

- Downstream Entities providing health care services:

The compliance program requirements described in this guide apply to healthcare providers contracted with BHN to provide healthcare services under at least one MA contract. This includes physicians, hospitals, and other provider types. Here is why:

- First, MA regulations and CMS rules state that a provider who contracts to provide healthcare services to Medicare enrollees with a First Tier Entity is a "Downstream Entity."
- CMS has listed examples of functions provided by a third party that are part of a First Tier Entity's contract with a MA plan. These include "health care services" and require that all Downstream Entities providing such services are in compliance with all applicable laws, rules, and regulations including CMS regulatory/sub-regulatory guidance.²

- Downstream Entities providing administrative services:

The compliance program requirements described in this guide also apply to entities with whom BHN contracts to perform administrative services in connection with BHN's MA contracts. Some examples of administrative services³ include:

- Claims administration, processing and coverage adjudications;
- Pharmacy claims processing at the point of sale;
- Negotiating with prescription drug manufacturers and others for rebates, discounts or other price concessions on prescription drugs;
- Hotline operations;
- Customer services;
- Licensing and credentialing; and
- Provider network management.

III. DOWNSTREAM COMPLIANCE PROGRAM AND ATTESTATION REQUIREMENTS

BHN can contract with Downstream Entities under our MA contracts, but BHN remains responsible for fulfilling our compliance obligations under those contracts – which includes that all contracting parties are in compliance with these obligations. Therefore, you (as our Downstream Entity) are also responsible for

² See MMCM Chapter 21 § 40.

³ See MMCM Chapter 21 § 40.

ATTACHMENT C: Downstream Entity Compliance Guide

meeting the relevant Medicare program requirements. It is important that you are in compliance with all applicable laws, rules, and regulations including CMS regulatory/sub-regulatory guidance.

Please refer to Section IV for specific requirements. If you use any subcontractors to meet your obligations to BHN under our contract, you are also responsible for ensuring that your Downstream subcontractors comply with these requirements, including, but not limited to, those in this guide.

A. What may happen if you don't comply:

If our Downstream Entities fail to meet these CMS compliance requirements, BHN may be found by the MA plans to not meet its contractual obligations and that may lead to:

- You developing a Corrective Action Plan (CAP) to help you resolve gaps;
- Training or retraining to prevent future non-compliance; or
- Contractual modification or termination of the contract by BHN.

BHN's actions in response to non-compliance will depend on the severity of the issue(s) and your response(s). If you identify an area of non-compliance (such as failing to screen your employees against the required exclusion lists), you must take prompt action to fix the situation and prevent it from happening again.

B. Attestation or audit requirements:

Each year, an authorized representative from your Organization must attest to your compliance with these requirements. This authorized representative is an individual who has responsibility directly or indirectly for all:

- Employees;
- Contracted personnel; and
- Providers/practitioners.

In addition, you may also be asked to provide evidence of your compliance with these obligations. The inability to produce this evidence may result in a request from BHN for a CAP or other contractual remedies up to and including contract termination.

Whether or not you are asked for it, you must maintain evidence of your compliance with these compliance program requirements for no less than ten (10) years.

IV. MEDICARE COMPLIANCE PROGRAM REQUIREMENTS

CMS requires⁴ that all FDRs meet all applicable federal healthcare statutes, regulations, and sub-regulatory guidance that are relevant to their contracts, and expects that FDRs have a mechanism to assure employees are aware of those requirements, i.e., training, testing, or other mechanisms.

There are several different program requirements that both BHN and any of its Downstream Entities (and their subcontractors) must meet. These requirements are more fully discussed below but include adoption and distribution of a Code of Conduct and compliance program policies; periodic exclusion list screening;

⁴ See 83 Fed Reg 16618 and C.F.R. § 422.503.

ATTACHMENT C: Downstream Entity Compliance Guide

mechanisms to report, assess for, and respond to possible compliance and FWA concerns; offshore activities reporting; oversight of your Downstream contractors; and evidence of meeting other applicable laws, rules, and regulations including CMS regulatory/sub-regulatory guidance.

A. Code of Conduct and Compliance Program Policies⁵

You must give your employees, volunteers, and board members standards of conduct (Code of Conduct, or CoC) and compliance program policies that meet the federal requirements outlined in footnote 4 provided below. In addition, you must assure that any Downstream Entities that you use to fulfill your contractual obligations under your agreement with BHN also provide a compliant CoC and compliance program policies to their employees.

The CoC and compliance program policies *must* be distributed:

- Within 90 days of hire/start or the Downstream Entity's contract effective date;
- Annually thereafter; and
- When there are updates to the CoC and policies.

In addition, evidence of the distribution of the CoC and compliance program policies to individuals and contractors must be retained for at least ten (10) years.

B. Reporting FWA and Compliance Concerns

There are a number of ways your workforce and contractors can report suspected or detected non-compliance or potential FWA, but one option must be a confidential and anonymous reporting system that you publicize. You must also adopt and enforce a non-retaliation policy that prohibits retaliation or intimidation against anyone that reports suspected misconduct or FWA in good faith.

In addition, you must be sure that you report these issues to BHN via one of the following methods:

- Anonymous reports can be made to BHN's toll-free ComplyLine at 1-888-747-7989 or online at <https://bannerhealthcomplyline.alertline.com>
- Email or call Teresa McMeans, BHN Compliance Officer:
 - Teresa.McMeans@bannerhealth.com
 - (602) 747-3140

Finally, when requested, evidence of such notification options and policies must be provided.

C. Exclusion List Screening⁶

Federal law prohibits federal health care programs such as Medicare, Medicaid, TRICARE, etc. from paying for services or items provided by a person or entity who has been excluded from participation in those programs. Therefore, before hiring an employee or contracting with an individual or an entity and then monthly thereafter, your Organization must check the required exclusion lists to confirm that your employees and contractors who are providing services under the BHN contract aren't excluded from participating in federal health care programs. You can use the following websites to perform the

⁵ See 42 C.F.R. § 422.503(b)(4)(vi)(A) and MMCM Chapter 21 § 50.1.1.

⁶ See § 1862(e)(1)(B) of the Social Security Act; 42 C.F.R. §§ 422.503(b)(4)(vi)(F), 422.752(a)(8), 423.504(b)(4)(VI)(F), 423.752(a)(6), 1001.1901; and MMCM Chapter 21 § 50.6.8.

required exclusion list screenings:

- OIG List of Excluded Individuals and Entities (LEIE): <https://exclusions.oig.hhs.gov>
- GSA's System for Award Management (SAM): <https://www.sam.gov>

You must maintain evidence that you have done these sanction screenings for each individual or contractor for at least ten (10) years.

BHN is also required to check these exclusion lists before hiring or contracting with anyone and monthly thereafter; however, we cannot check these lists for your employees and Downstream Entities. Therefore, to ensure that we comply with our CMS requirement, you must confirm that your permanent and temporary employees, volunteers, board members, leadership or owners and Downstream Entities/contractors that provide services under the BHN contract are not on either of these exclusion lists.

You *must* take action if an employee or Downstream Entity is on the exclusion list: (1) immediately remove the person or entity from work that is directly or indirectly related to BHN's contract; (2) determine if the person or entity is indeed excluded and, (3) if they are excluded *or* you cannot determine their status, immediately notify Banner Health Ethics & Compliance Department.

D. Monitoring/Auditing of Downstream Entities⁷

CMS requires that First Tier Entities, such as BHN, monitor the compliance of any Downstream Entities to assure that they comply with all applicable laws, rules, and regulations including CMS regulatory/sub-regulatory guidance. As a result of this obligation, BHN periodically audits its Downstream Entities, such as it is doing with your Organization, to ensure that all of the applicable laws, rules, and regulations are being met. You as a Downstream Entity must cooperate and participate in these activities. If you perform your own audits, we may ask for those audit results that affect BHN's contract. If we determine that a Downstream Entity is noncompliant with any of the requirements, we'll require the Downstream Entity to develop and submit a CAP to address the identified issues. A failure to correct these issues can lead to additional consequences which are unlikely, but can include, up to termination of the contract.

Further, CMS requires that these compliance obligations flow down through all levels of contractors that provide services that are part of meeting the clinical and administrative activities under MA contracts. So, if you choose to subcontract with other individuals/entities to meet your obligations under your contract with BHN, *you must also make sure that your subcontractors* abide by all laws, rules, and regulations applicable to BHN and you. These include:

- Medicare compliance programs as described in this guide; and
- Contractual agreements that contain all CMS-required provisions.

If you choose to use subcontractors, you *must* conduct sufficient oversight to test and ensure that they comply with the applicable laws, rules, and regulations, conduct analysis for problems and implement CAPs, meet the offshore requirements, and take disciplinary actions, as necessary, to prevent recurrence of non-compliance with applicable laws, rules, and regulations including CMS regulatory/sub-regulatory guidance, and retain evidence of your oversight and your subcontractors' compliance.

⁷ See 42 C.F.R. § 422.503(b)(4)(vi)(F) and MMCM Chapter 21 § 50.6.6.

E. Offshore Activities and CMS Reporting

To ensure that BHN meets the applicable federal and state laws, rules, and regulations including CMS regulatory/sub-regulatory guidance, you are prohibited from using any individual or entity that performs services under the BHN contract that is physically outside of the United States or one of its territories. The only exception is if an authorized BHN representative has expressly allowed the use of offshore services in advance and in writing.

If you perform services offshore or use an offshore entity to perform services involving the receipt, processing, transferring, handling, storing, viewing, creating, or otherwise accessing of PHI, and BHN approves the arrangement, BHN must submit an attestation to its MA plans. Those plans in turn will report the arrangement to CMS. You will need to provide the necessary information to BHN so that BHN can share it with the MA plans in order that it can be provided to CMS.

One example provided by CMS that triggers this requirement is “offshore subcontractors that receive radiological images for reading, because beneficiary PHI is included with the radiological image and the diagnosis is transmitted back to the U.S.”⁸ Another example is any coding or billing that is done outside of the U.S.

F. Other State and Federal Compliance Obligations

Based on the services that you provide under this contract, there may be other compliance obligations that you are subject to on the state or federal level, such as the Health Insurance Portability and Accountability Act (HIPAA) and the Payment Card Industry Data Security Standard (PCI). Even if it is not discussed here, BHN expects you and your Organization to be compliant with all applicable federal and state laws, rules, and regulations including CMS regulatory/sub-regulatory guidance as part of your contractual obligations and to have a mechanism to assure your employees are aware of the applicable requirements.

⁸ “Sponsor Activities Performed Outside of the United States (Offshore Subcontracting) Questions & Answers,” Centers for Medicare & Medicaid Services, at 2 (Sept. 20, 2007).