



# **ArchCare Advantage Compliance Policy**

For Health Care Providers and Business Partners

# Introduction

## Mission



**Scott LaRue**  
President and CEO

The mission of ArchCare is to foster and provide faith-based holistic care to frail and vulnerable people unable to fully care for themselves. Through shared commitments, ArchCare seeks to improve the quality of the lives of those individuals and their families.

ArchCare's dream is "to help people achieve lifelong well-being." In promoting this statement, ArchCare is committed to maintaining high ethical standards in the conduct of its business. The key to upholding these standards is through the daily decisions and actions of every ArchCare associate. Compliance is everyone's responsibility from the "top" to the "bottom" of the organization. This policy applies not only to our employees, but to our contractors and agents, our volunteers, our trustees, our affiliated medical staff and our vendors and sub-contractors.

The purpose of this policy is to assist our health care providers and business partners in fully understanding ArchCare's strong and explicit organizational commitment to conducting business ethically, with integrity, and in compliance with applicable laws, regulations, and requirements. ArchCare requires of its health care providers and business partners a similar commitment to ethical conduct and assurance that they, and their employees and downstream entities who support ArchCare business, comply with the guiding principles outlined within this policy.

## Organization

This policy articulates ArchCare's compliance requirements and expectations of its health care providers and business partners and addresses the requirements of the Centers for Medicare & Medicaid Services (CMS) pertaining to an effective compliance program and fraud, waste, and abuse prevention, detection, and correction. The main sections of this document incorporate the seven elements of an effective compliance program, with the first segment of each describing ArchCare's requirements and processes and the second segment, "Health Care Provider and Business Partner Impact," outlining ArchCare expectations of health care providers and business partners. Documentation and evidence of each impact item should be maintained for 10 years.

## Responsibility

ArchCare maintains ultimate responsibility for its compliance program's effectiveness. As part of this responsibility, ArchCare requires all health care providers and business partners to adhere to and maintain policies to address the principles outlined in this document. This can be achieved by adopting ArchCare's policy, maintaining similar internal policies that align with the guiding principles and requirements of this policy, or through completion of the exception process if the requirement is not applicable. Exception requests must be made in writing and receive approval from ArchCare's Compliance Department.

In addition, ArchCare has ongoing monitoring, auditing, and reporting processes to assess health care provider and business partner compliance. ArchCare will update this policy when there are material regulation, policy, or guidance changes, and at least annually.

# Definitions

**Abuse** – Includes any action(s) that may directly or indirectly, result in one or more of the following:

- Unnecessary costs to the health care system, including the Medicare program
- Improper payment for services
- Payment for services that fail to meet professionally recognized standards of care
- Services that are medically unnecessary

Abuse involves payment for items or services when there is no legal entitlement to that payment and the health care provider has not knowingly and/or intentionally misrepresented facts to obtain payment.

**Examples of abuse include:**

- Charging in excess for services or supplies
- Billing for items or services that should not be provided

Abuse cannot be differentiated categorically from fraud, because the distinction between “fraud” and “abuse” depends on specific facts and circumstances, intent, and prior knowledge, and available evidence, among other factors.<sup>1</sup>

**Associate** – Refers to an ArchCare employee.

**Audit** – Refers to a formal review of compliance with a particular set of internal (e.g., policies and procedures) or external (e.g., laws and regulations) standards used as base measures.

**Centers for Medicare & Medicaid Services (CMS)** – An agency within the U.S. Department of Health and Human Services that is responsible for the administration of the federal Medicare and Medicaid programs.

**Conflicts of Interest** – Personal, familial, or business relationships that could amount to, but are not limited to:

- Competing with any of ArchCare’s product offerings
- Providing services to a competitor of ArchCare
- Interfering with the performance of work duties

Please refer to ArchCare’s *Principles of Business Ethics for Health Care Providers and Business Partners* for examples.

**Downstream Entity** – An organization or individual that enters into an acceptable written arrangement below the level of the arrangement between ArchCare and a first tier entity. This continues down to the level of the ultimate provider of a service or product.

Example: A health care services group contracted directly with ArchCare is a first tier entity, and the hospitals and health care providers in the group are downstream entities. In addition, the group may contract with another company to perform billing and claims functions and that company is also a downstream entity.<sup>2</sup>

**Employees and Downstream Entities** – Individuals employed or contracted by a health care provider or business partner of ArchCare who are acting on behalf of ArchCare, either directly or indirectly. These include, but are not limited to, employees, employed and contracted health care providers and pharmacists, board members, pharmacy and therapeutic committee members, volunteers, consultants, and any contracted individuals.

**First Tier Entity** – An organization or individual that enters into an acceptable written arrangement with ArchCare to provide administrative or health care services.

Example: A call center contracted directly with ArchCare is a first tier entity.<sup>2</sup>

**Fraud** – Knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program or to obtain (by means of false or fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the custody or control of, any health care benefit program. (18 U.S.C. § 1347)

**Health Care Providers and Business Partners** – Organizations, individuals, or other entities contracted or subcontracted to provide a service or product for/to ArchCare, ArchCare-owned or ArchCare-operated facility/enterprise, an ArchCare affiliate, and/or to perform a function that ArchCare is responsible for performing. These may also be referred to as first tier, downstream, and related entities (FDRs). The definition includes, but is not limited to, health care providers, pharmacies, sales agents, sales agencies, delegates, vendors, suppliers, contractors, and related entities acting on behalf of ArchCare, either directly or indirectly, and continues down to the level of the ultimate provider of the service or product. It excludes wholly owned subsidiaries of ArchCare and their employees, as well as employees of ArchCare.

**ArchCare** – Refers to ArchCare Advantage, a coordinated care plan with a Medicare Advantage contract.

**Monitoring** – Reviews that are repeated regularly during the normal course of operations. These activities may occur to confirm:

- Ongoing compliance even in the absence of identified problems; or
- Corrective actions are undertaken and effective<sup>3</sup>

**Related Entity** – Any entity that is related to ArchCare by common ownership or control and meets one of the following criteria:

- Performs some of ArchCare’s management functions under contract or delegation;
- Furnishes services to enrollees under an oral or written agreement; or
- Leases real property or sells materials to ArchCare at a cost of more than \$2,500 during a contract period<sup>2</sup>

**Waste** – Overutilization of services or other practices that, directly or indirectly, result in unnecessary costs to the health care system, including the Medicare program. It is not generally considered to be caused by criminally negligent actions, but by the misuse of resources.<sup>1</sup>

<sup>1</sup> CMS Prescription Drug Benefit Manual, Chapter 9; Medicare Managed Care Manual, Chapter 21

<sup>2</sup> Adapted from 42 C.F.R. §422.500 and §423.501

<sup>3</sup> Adapted from <sup>1</sup>

# The Framework



## Written Policies, Procedures, and Standards of Conduct

ArchCare has two principle documents at the core of its compliance program:

- The *ArchCare Code of Conduct (ACC)* outlines ArchCare's standards of conduct and ethical expectations and can be accessed online at [www.ArchCare.org/compliance](http://www.ArchCare.org/compliance).
- The ArchCare Compliance Plan outlines the fundamental elements of ArchCare's compliance program, including
  - Required policies;
  - Compliance officer and Compliance Committee requirements;
  - Compliance and fraud, waste, and abuse (FWA) training content and requirements;
  - Communication and compliance officer access requirements;
  - Behavior monitoring and disciplinary standard expectations;
  - Requirements for monitoring and assessment of compliance with state and federal requirements and identification of compliance risks; and
  - Requirements for identifying, responding to, and correcting compliance issues.

Numerous policies, standards, and procedures exist to support the Compliance Plan. The core policies that apply to relationships with health care providers and business partners as they relate to compliance are outlined in this document.

### Health Care Provider and Business Partner Impact Policies, Procedures, and Standards of Conduct

Health care providers and business partners are expected to either adopt ArchCare's *ACC* or maintain their own, similar supplemental version of the standards of conduct. In addition, health care providers and business partners are expected to either adopt this compliance policy or maintain their own, similar policies that support the requirements and activities in this document. Supporting procedures may be developed and maintained for certain required activities. All health care providers and business partners are required to have appropriate policies and procedures in place to address FWA.

### Record Retention

Health care providers and business partners must maintain documentation and records for requirements and activities outlined in this policy for 10 years.

## Relationships With Downstream Entities

Though ArchCare is ultimately responsible for any functions performed to support its business, there are also certain requirements that health care providers and business partners must adhere to when entering into a relationship with a downstream entity. The health care provider or business partner must:

- Notify ArchCare for approval to subcontract any services inside or outside of the United States
- Maintain adequate written agreements with downstream entities
- Maintain adequate oversight of the functions performed downstream
- Confirm that downstream entities adhere to core compliance requirements, including all requirements outlined in this document (such as providing compliance and FWA training, exclusion screening, and monitoring and auditing of any further downstream entities)



## Compliance Officer and Compliance Committee, and High Level Oversight

ArchCare has a Medicare Compliance Officer (MCO) who is a full-time ArchCare associate and chairs the ArchCare Compliance Committee. The MCO, on behalf of the Compliance Committee, reports directly to the Board of Trustees. The MCO reports indirectly to the chief executive officer (CEO), and administratively to the senior vice president and vice-president of compliance, and has direct access to report any compliance matters to the Board of Trustees or chief executive officer.

The MCO, vice-president of compliance, chairman of the board and CEO, and the board of trustees provide overall leadership and governance for the ArchCare Compliance Plan.

### Health Care Provider and Business Partner Impact

Health care providers and business partners are expected to have a designated compliance resource accountable for overseeing the organization's compliance responsibilities, including those outlined in this document. The personnel assigned must be adequately educated, trained, and qualified to perform compliance functions. ArchCare is not prescriptive regarding specific qualifications; however, organizations may choose to consider qualifications such as formal education, on the job training, industry experience, compliance experience, continuing education, conferences, and seminars in determining adequacy.

# Communication



## Effective Training and Education

ArchCare requires its associates to annually review the associate version of the ACC. In addition, associates and members of the board of directors receive compliance and FWA training within 30 days of hire or election and annually thereafter. Associates working in areas of identified substantial risk receive specialized and focused training. These areas include, but are not limited to the following: Claims, Billing and Enrollment, Sales, Grievance and Appeals, Pharmacy, and Privacy.

Health care providers and business partners are required to review the supplemental ACC and complete compliance and FWA training within 90 days of contract and annually thereafter. They are also required to provide standards of conduct and compliance and FWA training employees and any downstream entities. Health care providers and business partners may use their discretion in how training is administered; examples include classroom training, online training modules, or attestations that employees have read and received standards of conduct and/or compliance policies and procedures. These entities may choose to complete required compliance and FWA training through other sources (their own training program, other health plans, CMS training, etc.). CMS has developed and published a FWA training module that meets CMS requirements. Instructions for accessing the training are available in Appendix A. Regardless of the method used for training, health care providers and business partners are required to provide proof to ArchCare that the requirement has been met through completion of an acceptance statement and maintenance of documentation of the time, attendance topic, certifications of completion, and test scores of any tests administered (if applicable).

### Required Training and Education

All employees and downstream entities of health care providers and business partners are required to receive:

- General compliance training (including Medicare compliance training, if applicable)
- FWA prevention training
- Applicable, job-specific compliance training

Individuals with ArchCare system access are required to complete ArchCare's training(s) and are not required to receive additional training for the following elements:

- General compliance
- FWA

Sufficient understanding of training received must be demonstrated to the health care provider or business partner prior to performing any functions included under a ArchCare contract, which may be accomplished through knowledge checks or other means. ArchCare will provide training content support and monitor completion of required training to those who have ArchCare system access.

### Required Training Timelines

All health care providers and business partners must train on compliance and FWA within 90 days of hiring an employee, including a temporary employee, appointing a new board member or contracting with a representative, or downstream entity. Those employees or downstream entities who receive ArchCare system security access are required to take ArchCare's training on ethics and compliance, including FWA, within 30 days of receiving such access. Additionally, job-specific training must be provided by health care providers and business partners and completed within 30 days of hire or contract to properly perform the functions required.

### Deemed Status

ArchCare recognizes that certain health care providers are deemed to have met FWA education and training requirements through:

- Enrollment into the Medicare program or
- Accreditation as a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)

In the case of organizations with multiple locations, such as chain pharmacies, each individual location must be enrolled in Medicare Part A or B to be deemed.

### Noncompliance With ArchCare's Training Requirements

The following will occur in the event that any non-deemed employee or downstream entity of a health care provider or business partner is found to be noncompliant with respect to ArchCare's training requirements or an individual's singular actions demonstrate noncompliance with ArchCare's compliance expectations:

- ArchCare will give the organization written notice
- The health care provider or business partner must immediately remove and replace such employee or downstream entity at its expense

If the health care provider or business partner discovers the noncompliant actions, then the health care provider or business partner must remove and replace the employee or downstream entity and notify ArchCare. In the event that the health care provider or business partner fails to immediately remove and replace the noncompliant employee or downstream entity, as requested by ArchCare, then ArchCare may take disciplinary action, up to and including, termination of the contracted work upon written notice.

### Changes Impacting Training

ArchCare will notify health care providers and business partners when there are changes to a process in a specific contract that require immediate, job-specific training and require the health care provider or business partner to act immediately to provide such training to its employees and any downstream entities.

### Health Care Provider and Business Partner Impact

Health care providers and business partners are expected to:

- Complete ArchCare's compliance and FWA training within 90 days of contract and annually thereafter.
- Provide compliance policies and standards of conduct to employees and any downstream entities within 90 days of hire or contract and annually thereafter.
- Provide compliance and FWA training to employees and any downstream entities within 90 days of hire or contract and annually thereafter. Training documentation should include the time, attendance, topic, certificates of completion (if applicable), and test scores of any tests administered.
- Verify as deemed, or remove and replace, any employees and any downstream entities who do not receive FWA training within 90 days of hire or contract through proper credentialing.
- Provide specialized compliance training on issues posing FWA risks based on an individual's job function when appropriate.

### Effective Lines of Communication

ArchCare communicates with its associates through various media to provide continual awareness of the importance of compliance. ArchCare also communicates regularly with its health care providers and business partners through a variety of methods, including contracts, administration manuals, newsletters, policy communication, and annual compliance and FWA training.

#### Access and Availability of Compliance Officer

In addition, the Medicare and Medicaid compliance officer, Victor B. Fama, is available to any associate, health care provider, or business partner with suggestions or comments on maintaining ethical behavior, or identifying and preventing fraudulent or criminal misconduct, or they may contact the Compliance Hotline at 1-800-443-0463.

Mr. Fama is based in ArchCare's managed care headquarters:  
33 Irving Place, New York, NY 10003;  
telephone: 917-484-5055.

#### Requirement to Report

All ArchCare associates, members of the governing body, health care providers, and business partners are required to report compliance concerns and suspected or actual compliance and FWA violations to ArchCare.

#### Methods for Reporting Suspected or Detected Noncompliance to ArchCare

If health care providers, business partners, or their employees or downstream entities suspect or detect a violation of ArchCare's ACC or any related law or policy, they should immediately report it to ArchCare through one of the following methods:

- **Telephonic:** Compliance Hotline 1-800-443-0463
- **Online:** Compliance Web reporting site [www.archcare.org/health-plans/archcare-advantage/reporting-fraud-waste-abuse](http://www.archcare.org/health-plans/archcare-advantage/reporting-fraud-waste-abuse)
- **Email:** [ComplianceReport@ArchCare.org](mailto:ComplianceReport@ArchCare.org) (Compliance Office) or to your Compliance Officer

### Key Features of These Communication Options

- **Neutrality:** Non-ArchCare personnel (employed by a separate company) staff the Compliance Hotline.
- **Anonymous Reporting:** Communication to the Compliance Hotline or Compliance Web reporting site can be made anonymously. ArchCare requests that if a reporter desires to remain anonymous, he/she provide enough information to allow ArchCare to investigate the issue.
- **Prohibition Against Intimidation and/or Retaliation:** ArchCare strictly prohibits intimidation and/or retaliation against any health care provider or business partner, or their employees or downstream entities, who, in good faith, reports a detected or suspected violation of ethical standards or FWA.
- **Status Update:** Regardless of the reporting method used, the individual reporting a suspected or detected violation will receive a confidential identification number that will allow for follow-up on the status of the issue reported. The Compliance Web reporting site also provides a recommended follow-up date.

### Health Care Provider and Business Partner Impact

Health care providers and business partners may train their employees and downstream entities on their own reporting processes; however, the reporting system must meet the following requirements:

- Maintain confidentiality (to the greatest extent possible)
- Allow for anonymity if desired
- Be available 24 hours a day
- Emphasize the policy of non-intimidation and non-retaliation for good faith reporting of compliance concerns, FWA, and participation in the compliance program
- Emphasize that reports must be made to ArchCare

In addition, health care providers and business partners are expected to:

- Widely publicize the methods for reporting compliance and FWA concerns and the non-retaliation policy throughout facilities (examples include: posters, table tents, mouse pads, key cards, and other prominent displays)
- Reinforce ArchCare's policy of non-intimidation and non-retaliation
- Report compliance concerns and suspected or actual compliance and FWA violations to ArchCare.



# Investigation, Discipline and Correction

## Disciplinary Standards



Violation of ArchCare's ACC and other policies and procedures could compromise ArchCare's integrity and reputation. A violation may also result in a required corrective action, termination of contract, and/or reporting of the violation to appropriate regulatory and/or law enforcement authorities.

ArchCare initiates investigations of any reports of suspected or detected violations of its ACC and ArchCare policies and procedures, as well as FWA, as quickly as possible, but not later than within two weeks of identifying the suspected or detected issue. All reported issues are treated confidentially to the greatest extent possible and documentation is maintained.

In the event that corrective actions are imposed on a health care provider or business partner, ArchCare will monitor and/or audit the health care provider or business partner to confirm that corrective actions have been implemented. Monitoring and auditing following implementation will also occur, as appropriate, to facilitate effective corrective actions.

## Health Care Provider and Business Partner Impact

Health care providers and business partners are expected to:

- Widely publicize the disciplinary standards, including the duty and expectation to report noncompliant and unethical behavior and suspected FWA
  - Examples include: newsletters, regular presentations and department staff meetings, communications with downstream entities, general compliance training, intranet site, posters prominently displayed throughout employee work and break areas, and cafeteria table tents.
- Take prompt disciplinary action when there is noncompliant or unethical behavior by their employees or downstream entities or FWA is discovered, and report such action to ArchCare.
  - ArchCare reserves the right to take additional action if deemed necessary.
- Cooperate fully with any investigation of an alleged violation and/or remedial actions.

# Oversight

## Monitoring and Auditing Work Plan



ArchCare maintains a plan for continuous monitoring of potential fraud, waste, and abuse activity. ArchCare monitors and audits the activities of associates, members of its health plans and insurance policies, health care providers, and business partners. In addition, health care providers and business partners are responsible for maintaining their own comprehensive plan for detecting, correcting, and preventing fraud, waste, and abuse.

ArchCare also conducts monitoring and auditing activities for its relationships with health care providers and business partners. The activities monitored and audited may include, but are not limited to, both operational performance and compliance requirements applicable to the functions performed and as described throughout this document.

ArchCare has developed separate monitoring and auditing work plans to address the risks associated with the health care provider and business partner relationships. The implemented work plans enable ArchCare to determine the nature, timing, and extent of the monitoring and auditing process to be performed by ArchCare.

Periodically, ArchCare may submit a request to the health care provider or business partner to complete a self-assessment, questionnaire, or survey, submit documentation, attest to applicable policy, procedure, and compliance requirements, and/or to schedule an onsite audit, which may include a review of the organization's operational and compliance performance. This may include, but is not limited to, inspection of the facilities, systems, books, procedures, audit work plans and results, and records that relate to the services of the health care provider or business partner under the contractual agreement in order to monitor and/or audit compliance with the contractual agreement. Health care providers and business partners shall provide timely turnaround of these requests in accordance with the time period specified by ArchCare.

Disciplinary actions could result from ArchCare's conducted monitoring and auditing initiatives. These could include, but are not limited to: mandatory (re)training, corrective action plans, or contract termination.

### Health Care Provider and Business Partner Impact

Health care providers and business partners are expected to:

- Monitor for fraud, waste, and abuse within their organizations and downstream entities
- Comply with any monitoring or auditing requests from ArchCare
- Develop and implement monitoring and auditing work plans for any functions supporting ArchCare business that the health care provider or business partner has further contracted to downstream entities

### Exclusion Lists

Individuals and entities appearing on either the Department of Health and Human Services (DOH), Office of Inspector General List of Excluded Individuals and Entities (OIG) or the General Services Administration list of excluded parties contained within the System for Award Management (GSA) may not support any ArchCare business function. All health care providers and business partners, and their employees and downstream entities, are required to be screened against both the OIG and the GSA prior to hire or contract and monthly thereafter.

### Health Care Provider and Business Partner Impact

Health care providers and business partners are expected to:

- Query the OIG, and GSA for all employees and downstream entities prior to hire or contract and monthly thereafter
- Promptly remove any individual or entity appearing on either of these lists from any work related to ArchCare business functions

- Promptly report any such exclusions and actions to ArchCare

### Conflicts of Interest

ArchCare requires all employees to complete a conflict of interest statement certifying that the individual is free from any conflicts of interest in performing his/her job function. Similarly, employees and downstream entities of ArchCare's health care providers and business partners must be screened for conflicts of interest within 90 days of hire or contract and annually thereafter. Employees and downstream entities should disclose potential conflicts of interest as soon as they become aware of the conflict.

### Health Care Provider and Business Partner Impact

Health care providers and business partners are expected to:

- Obtain conflict of interest statements from their employees and downstream entities within 90 days of hire or contract and annually thereafter
- Review potential conflicts of interest and either remove the conflict or, if appropriate, grant approval to continue work despite the conflict

## Appendix A: Resources

### CMS Medicare Parts C and D Fraud, Waste, and Abuse Training

1) Navigate to the link below; 2) Scroll to the "Downloads" section; 3) Click on "Medicare Parts C and D Fraud, Waste, and Abuse Training"; 4) Select "Open" or "Save"; the training is available in both PDF and PowerPoint formats

<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ProviderCompliance.html>

### CMS Compliance Program Policy and Guidance

Care Manual

<http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Compliance-Program-Policy-and-Guidance.html>



# Appendix B: Applicable Laws and Regulations

Note: Depending on the function your organization performs, not all of the following laws and regulations may be applicable to it.

## Title XVIII of the Social Security Act

Passed in 1965, the Social Security Act included Title XVIII, which became known as Medicare. Title XVIII includes Part A, which provides hospital insurance for the aged and disabled, and Part B, which provides medical insurance. To address the Part A and Part B benefits, Medicare offers a choice between an open-network single payer health care plan (known as Original Medicare) and plans administered by private companies approved by Medicare (Medicare Advantage, or Medicare Part C), where the federal government pays for private companies to administer health coverage. Medicare Part D covers outpatient prescription drugs exclusively through plans offered by Medicare-approved private insurance companies. Part D plans can either be standalone prescription drug plans or through included in a Medicare Advantage plan that offers prescription drugs. ArchCare offers part C and D plans, therefore, the laws and regulations related to Part C and D plans, many of which are listed below, impact your relationship with ArchCare.

[http://www.ssa.gov/OP\\_Home/ssact/title18/1800.htm](http://www.ssa.gov/OP_Home/ssact/title18/1800.htm)

## Medicare regulations governing Parts C and D found at 42 C.F.R. §§ 422 and 423 respectively

CMS has outlined compliance program guidelines in its Prescription Drug Benefit Manual, Chapter 9 and Medicare Managed Care Manual, Chapter 21. That combined manual is an interpretation of the compliance program requirements and related provisions in C.F.R. §§ 422 and 423 for Medicare Advantage Organizations (MAO) and Medicare Prescription Drug Plans (PDP). As a result, ArchCare's compliance program incorporates the seven elements of an effective program as outlined by CMS.

C.F.R. §§ 422: <http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&rgn=div8&view=text&node=42:3.0.1.1.9.11.5.4&idno=42>

C.F.R. §§ 423: <http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=a21771a0a11cfa4a79180b600ec6093f&rgn=div8&view=text&node=42:3.0.1.1.10.11.6.5&idno=42>

## Patient Protection and Affordable Care Act (Pub. L. No. 111-148, 124 Stat. 119)

This extensive act is most known for the increased rights and protections it establishes for consumers, but it has many provisions, known as titles. The core elements of this act include, but are not limited to, the following:

- Where/how to purchase coverage is being expanded
- New benefits are offered for those eligible for coverage
- There are shifts in who is eligible for receiving and retaining coverage and under what arrangements
- Organizations offering insurance, like ArchCare, are subject to greater accountability

The act will change payment (amounts) and reimbursement(s) for certain benefits, as well as increase the ability to appeal claims, which may impact enrollment and claims processing. This could ultimately affect your relationship with ArchCare and/or how your organization maintains records and/or tracks payments.

There are other titles that could also impact your organization, although not directly in regard to ArchCare. Therefore, the act is available here for review:

<http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>

## Health Insurance Portability and Accountability Act (HIPAA) (Public Law 104-191)

Per the U.S. Department of Labor, HIPAA was initially passed in 1996 to "improve portability and continuity of health insurance coverage." As a result, there are more consumer protections regarding options for coverage.

<http://aspe.hhs.gov/admsimp/pl104191.htm>

Later "rules," or provisions, were passed in 2001 and 2003 to protect the privacy, confidentiality, and security of individually identifiable health information. This includes the establishment of security standards for electronic protected health information.

Your organization, as well as ArchCare, is required to have sufficient safeguards regarding this type of information, including who may access it, how much of it may be accessed by any individual, and how it is retained and transmitted.

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html>

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsummary.html>

## False Claims Acts (31 U.S.C. §§ 3729-3733)

This act gives the federal government leverage against persons/entities involved in fraudulent activities with the government. This allows financial liability in the form of a civil penalty and damages to be imposed for submitting, or causing someone to submit, a false or fraudulent claim for government payment.

<http://www.gpo.gov/fdsys/pkg/USCODE-2011-title31/pdf/USCODE-2011-title31-subtitleIII-chap37-subchapIII-sec3729.pdf>

<http://www.gpo.gov/fdsys/pkg/USCODE-2011-title31/pdf/USCODE-2011-title31-subtitleIII-chap37-subchapIII-sec3730.pdf>

<http://www.gpo.gov/fdsys/pkg/USCODE-2011-title31/pdf/USCODE-2011-title31-subtitleIII-chap37-subchapIII-sec3731.pdf>

<http://www.gpo.gov/fdsys/pkg/USCODE-2011-title31/pdf/USCODE-2011-title31-subtitleIII-chap37-subchapIII-sec3732.pdf>

<http://www.gpo.gov/fdsys/pkg/USCODE-2011-title31/pdf/USCODE-2011-title31-subtitleIII-chap37-subchapIII-sec3733.pdf>

**Federal Criminal False Claims Statutes (18 U.S.C. §§ 287,1001)**

Section 1001 applies to anyone whose action(s) related to any claim(s) for government payment consist(s) of any of the following:

- Falsifying, concealing, or covering up by any trick, scheme, or device a material fact related to any claim(s) for government payment;
- Making any materially false, fictitious, or fraudulent statement or representation;
- Making or using any false writing or document knowing it contains any materially false, fictitious, or fraudulent statement or entry.

Section 287 states that whoever makes or presents to the government a claim knowing that it is false, fictitious, or fraudulent shall be imprisoned and subject to fines. The government is required to establish all of the following in regard to the action(s) of a false claim(s) case defendant. He/she:

- Made or presented a false, fictitious, or fraudulent claim to a department of the United States;
- Knew the claim was false, fictitious or fraudulent; and
- Did so with the specific intent to violate the law or with awareness that what s/he was doing was wrong.  
<http://www.gpo.gov/fdsys/pkg/USCODE-2011-title18/pdf/USCODE-2011-title18-partI-chap15-sec287.pdf>  
<http://www.gpo.gov/fdsys/pkg/USCODE-2011-title18/pdf/USCODE-2011-title18-partI-chap47-sec1001.pdf>

**Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))**

This federal statute prohibits any individual or entity from knowingly and deliberately offering, giving, or receiving money or something of value in exchange for referrals of health care goods or services that will be paid for in whole or in part by Medicare or Medicaid.

[http://www.ssa.gov/OP\\_Home/ssact/title11/1128B.htm#f](http://www.ssa.gov/OP_Home/ssact/title11/1128B.htm#f)

**The Beneficiary Anti-Inducement Statute (42 U.S.C. § 1320a-7a(a)(5))**

This federal statute declares that any person who gives or offers to give anything of value\* to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence a beneficiary's choice of a particular health care provider, practitioner, or supplier to buy or rent a Medicare or Medicaid covered item from the provider, practitioner, or supplier may be liable for civil money penalties of up to \$10,000 for each each wrongful act.

<http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap7-subchapXI-partA-sec1320a-7a.pdf>

\* The OIG stated in guidance that there is a "nominal value" exception that allows a health care provider to give:

- A gift to a beneficiary as long as the gift has a retail value of \$10 or less
- Multiple gifts of \$10 or less over a 12-month period, as long as the total retail value of the gifts does not exceed \$50

Any such gift must not be in cash or cash equivalents, so it should not be a gift card or gift certificate. Types of gifts and their value(s) are detailed in a Special Advisory Bulletin from the OIG: <https://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>

**Prohibitions against employing or contracting with persons or entities that have been excluded from doing business with the federal government (42 U.S.C. §1395w-27(g)(1)(G))**

The expectations of CMS and ArchCare in regard to screening government exclusion lists have been outlined in the oversight section on page 9 of this policy and in this federal provision:

<http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap7-subchapXVIII-partC-sec1395w-27.pdf>

**Civil monetary penalties of the Social Security Act (42 U.S.C. § 1395w-27 (g))**

This provision of the Social Security Act describes the penalties that can be assessed to organizations that offer Part C and/or Part D plans should CMS determine they do not meet the requirements outlined in their contract(s) with CMS. Your organization is impacted by this act if it supports and/or sells any of ArchCare's Medicare Advantage or Prescription Drug products. Examples of such impactful provisions include, but are not limited to:

- Enrolling an individual in any such plan without the prior consent of the individual or the individual's designee
- Failing to re-enroll an eligible individual
- Denying or discouraging an eligible individual from plan enrollment
- Noncompliance with marketing restrictions surrounding these plans
- Failing substantially to provide medically necessary items and services that are required (under law or contract) to an individual covered under the contract

<http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap7-subchapXVIII-partC-sec1395w-27.pdf>

Physician Self-Referral ("Stark") Statute (42 U.S.C. § 1395nn)

This statute:

- Prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception\* applies
- Prohibits the entity from presenting, or causing to be presented, claims to Medicare (or billing another individual, entity, or third party payer) for those referred services

\* Specific exceptions have been established, and the federal government has the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

Please refer to the following link for a list of the established exceptions and additional information:  
<https://www.cms.gov/PhysicianSelfReferral/>

Fraud and Abuse, Privacy and Security Provisions of the Health Insurance Portability and Accountability Act, as modified by HITECH Act

This act could be considered an extension of HIPAA, as it enabled the U.S. Department of Health and Human Services to promote and expand the adoption of health information technology. It addresses:

- Use of electronic health records, including incentives for adopting them and requirements around their disclosure
- How to secure protected health information appropriately
- When and to whom notifications should be made in regard to data breaches of unsecured protected health information (PHI)

<http://www.healthit.gov/policy-researchers-implementers/final-rules-regulations>

Fraud Enforcement and Recovery Act of 2009

This act improves the enforcement of various kinds of fraud related to federal assistance and relief programs, the recovery of funds lost to these frauds, and for other purposes. It increased resources for investigation and prosecution of fraud cases and made recovery under the False Claims Act, 31 USC § 3729 statute easier.

<http://www.gpo.gov/fdsys/pkg/PLAW-111publ21/pdf/PLAW-111publ21.pdf>

CMS Data Use Agreement

ArchCare's *Compliance Policy* and *ACC* incorporate the overarching aspects of the CMS Data Use Agreement to facilitate the proper safeguarding of all data, including CMS-related data, by ArchCare and health care providers and business partners, regardless of whether support is provided for ArchCare's Part C and/or Part D offerings.

The overarching components of the CMS Data Use Agreement are as follows:

**Disclosure**, use, or reuse of the data covered by the agreement between CMS and ArchCare must only be for the purpose(s) specified within the agreement, unless CMS provides appropriate authorization for any other purpose(s).

- Any individual's access to the data must only be on a need-to-know basis
- Data access must be limited to the minimum amount of data and minimum number of individuals necessary to achieve the purpose stated in the agreement

**Sufficient Data Safeguards** for the storage and disclosure of data/information must be established from the following perspectives: administrative, technical, and physical. Together these measures assure data confidentiality is protected and that unauthorized use or access to it is prevented.

**Handling of Suspected or Detected Breaches**

- This matter is addressed in the Effective Communications section of this policy under "Methods for Reporting Suspected or Detected Noncompliance to ArchCare"

A signed CMS Data Use Agreement provides CMS with assurance of compliance with the requirements of the Privacy Act, the Privacy Rule, and CMS data release policies when CMS data is utilized by anyone outside of CMS. The agreement must be completed and updated when applicable by ArchCare. Upon CMS' receipt of the completed agreement, CMS provides ArchCare with, and/or access to, data containing, but not necessarily limited to, protected health information and individual identifiers from CMS' Systems of Record. It is your responsibility to consult with your legal counsel to determine when/if there are instances that the CMS Data Use Agreement applies to your organization.

All sub-regulatory guidance produced by CMS and HHS such as manuals, training materials, HPMS memos, and guides

Vast guidance resources are available on the following websites:

**CMS:** <https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance.html>  
<http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html>

**U.S. Department of Health and Human Services:**

<http://www.hhs.gov/>  
<http://www.hhs.gov/regulations/index.html>