



2021

First Tier, Downstream,
& Related Entity (FDR)
and
Affiliate Compliance Guide

To report suspected
fraud and abuse or other
violations of company policy,
call 1-877-879-9137 or go to
www.hfcompliance.ethicspoint.com

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Healthfirst Compliance Program

Healthfirst's Compliance Program is designed to reduce or eliminate fraud, waste, abuse, and inefficiencies; to ensure Healthfirst's compliance with applicable regulations; and to reinforce Healthfirst's commitment to **zero tolerance** for such activities.

Healthfirst has a legal requirement to provide information and education to those individuals, entities, businesses, and providers with whom we work. The Centers for Medicare and Medicaid Services (CMS), New York Office of Medicaid Inspector General (OMIG), and various other agencies provide guidance and regulatory oversight of our Compliance Program.

Additional information on the Healthfirst Compliance Program is available upon request by contacting the Compliance department or by visiting our website at <https://healthfirst.org/fraud-and-compliance/> and selecting *Guide to the Compliance Program*.

Introduction to the First Tier, Downstream, & Related Entity (FDR) and Affiliate Compliance Guide

The FDR and Affiliate Compliance Guide is a resource designed to assist our FDRs and Affiliates with understanding and complying with the Healthfirst Compliance Program and its requirements. This guide will:

- demonstrate Healthfirst's commitment to responsible corporate conduct;
- set forth the FDRs and Affiliates compliance requirements;

- publicize mechanisms for reporting fraud, waste, abuse, and compliance issues;
- communicate information about the Healthfirst Code of Conduct and the compliance policies in place to detect, prevent, correct, and monitor fraud, waste, abuse, and inefficiencies;
- define and provide examples of fraud, waste, and abuse; and
- provide information about relevant laws and regulations.

Section 1: What is an FDR or Affiliate?

Healthfirst utilizes the Centers for Medicare and Medicaid Services' (CMS) current definitions to define First Tier, Downstream, and Related Entities (FDRs):

A **First Tier Entity** is any party that enters into a written arrangement, acceptable to CMS, with a Medicare Advantage Organization or Part D plan sponsor or applicant to provide administrative services or healthcare services to a Medicare-eligible individual under the Medicare Advantage program or Part D program.



A **Downstream Entity** is any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Medicare Advantage benefit or Part D benefit, below the level of the arrangement between a Medicare Advantage 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.

Related Entity means any entity that is related to a Medicare Advantage Organization or Part D sponsor by common ownership or control and:

- (1) performs some of the Medicare Advantage Organization's or Part D plan Sponsor'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 Medicare Advantage Organization or Part D plan Sponsor at a cost of more than \$2,500 during a contract period.

An **Affiliate** is a person, provider, or entity who provides care, services, or supplies under the Medicaid program, or a person who submits claims for care, services, or supplies for or on behalf of another person or provider for which the Medicaid program is or should be reasonably expected by a provider to be a substantial portion of their business operations.

Section 2: FDR and Affiliate Compliance Requirements

Healthfirst's commitment to compliance includes ensuring that our First Tier, Downstream, and Related Entities (FDRs) and Affiliates are in compliance with applicable state and federal regulations. Healthfirst contracts with these entities to provide administrative and healthcare services to our enrollees; we are ultimately responsible for fulfilling the terms and conditions of our contract with CMS and for meeting the Medicare and Medicaid program requirements. Therefore, Healthfirst requires each FDR and Affiliate to comply with the compliance and fraud, waste, and abuse expectations below. Failure to meet the requirements may lead to a Corrective Action Plan, retraining, or the termination of a contract and relationship with Healthfirst.

First Tier Entities are responsible for ensuring that their downstream and related entities are in compliance with this policy and with applicable Federal and State statutes and regulations.



FDRs and Affiliates must maintain supporting documentation of compliance with the requirements below for a period of 10 years and must furnish evidence to Healthfirst upon request for monitoring and auditing purposes.

I. Annual FDR and Affiliate Compliance Attestation

An authorized representative from each FDR and Affiliate is required to complete the Healthfirst FDR and Affiliate Compliance Attestation (on behalf of their organization) upon contract and on an annual basis thereafter, to attest to compliance with the standards of conduct; compliance policies; OIG¹, GSA (SAM)² and OMIG exclusion screenings; and publication of FWA and compliance reporting mechanisms requirements.

An authorized representative is an individual who has direct or indirect responsibility for all employees, contracted personnel, providers/practitioners, and vendors who provide healthcare or administrative services under Medicaid and/or Medicare. Authorized representatives may include, but are not limited to, a Compliance Officer, Chief Medical Officer, Practice Manager/Administrator, Provider, an Executive Officer, or similar related positions.

Healthfirst will send a notification to each FDR and Affiliate to communicate the deadline for completion of the annual attestation. All FDRs and Affiliates must complete attestations within the designated timeframe.

¹Office of Inspector General

²General Services Administration (GSA), now the System for Award Management

II. Standards of Conduct and Compliance Information

Healthfirst requires each FDR and Affiliate to establish and sustain a culture of compliance. Healthfirst FDRs and Affiliates must either (1) establish and publicize comparable Standards of Conduct that meet CMS requirements set forth in 42 CFR § 422.503(b)(4)(vi)(A) and 42 CFR § 423.504(b)(4)(vi)(A) and reflect a commitment to preventing, detecting, and correcting noncompliance, or (2) adopt and distribute to all employees and contractors Healthfirst's Standards of Conduct, which can be found in this guide.

In addition to the Standards of Conduct, each FDR and Affiliate must distribute compliance information to all employees and contractors upon hire/contract and annually thereafter. Healthfirst provides compliance information in this guide that can be utilized. If an FDR or Affiliate opts to use different material, it must include, at minimum, a description of the Compliance Program, instructions on how to report suspected noncompliance, the requirement to report potential noncompliance and FWA, disciplinary guidelines for noncompliant behavior, a non-retaliation provision, a FWA training requirement, and an overview of relevant laws and regulations (such as the Deficit Reduction Act of 2005, False Claims Act, and HIPAA).



FDRs and Affiliates must maintain records (i.e., attestations, logs, etc.) to document that each employee and contractor has received, read, understood, and will comply with the written standards of conduct and compliance policies upon hire/contract and annually thereafter.

III. OIG and GSA (SAM) and NYS Exclusion Screening (OMIG)

Federal law prohibits the payment by Medicare, Medicaid, or any other federal healthcare program for any item or service furnished by a person or entity excluded from participation in these federal programs. Therefore, prior to hire and/or contract and monthly thereafter, each FDR and Affiliate must confirm that their employees and contractors are not excluded from participation in federally funded healthcare programs, according to the OIG and GSA (SAM) and the NYS exclusion (OMIG) lists.

Use the websites below to perform the required screening:

- <http://exclusions.oig.hhs.gov>
- <https://sam.gov/search/>
- https://apps.omig.ny.gov/exclusions/ex_search.aspx

If an employee or contractor is on an exclusion list, they must be removed from any work related directly or indirectly to federal healthcare programs, and appropriate corrective action must be taken.

FDRs and Affiliates must maintain evidence of exclusionary checks (i.e., logs or other records) to document that each employee and contractor has been screened in accordance with current regulations and requirements.



IV. Reporting Fraud, Waste, Abuse, and Compliance Issues

Healthfirst FDRs and Affiliates have a responsibility to report any alleged compliance; fraud, waste, and abuse; and/or conflict of interest issues that involve Healthfirst. FDRs and Affiliates may use the following methods to confidentially report a potential violation of our compliance policies or of any applicable regulation without fear of retaliation:

Healthfirst Reporting

- Healthfirst's 24/7, confidential & anonymous hotline **1-877-879-9137** or online at www.hfcompliance.ethicspoint.com
- Compliance Officer,
100 Church Street, New York, NY 10007
Email – compliance@healthfirst.org
- Special Investigations Unit,
100 Church Street, New York, NY 10007
Email – SIU@healthfirst.org

Medicare Reporting

- Office of Inspector General at **1-800-HHS-TIPS (1-800-447-8477)**, **TTY 1-800-377-4950**
- Centers for Medicare and Medicaid Services (CMS) at **1-800-MEDICARE (1-877-486-2048)** or by mail at Medicare, Attention: Beneficiary Contact Center, P.O. Box 39, Lawrence, KS 66044
- For additional information on how to detect and report Medicare fraud, you may access this link at <https://www.medicare.gov/forms-help-resources/help-fight-medicare-fraud>

NY Medicaid Reporting

- Fraud Hotline **1-877-873-7283** or online at <https://omig.ny.gov/medicaid-fraud/file-allegation>

Healthfirst requires each FDR and Affiliate to publicize confidential reporting mechanisms for all employees and contractors. If an FDR/Affiliate does not maintain a confidential reporting mechanism, the Healthfirst Confidential Hotline and website information must be distributed to encourage reporting of potential compliance issues; fraud, waste, and abuse; conflicts of interest; or violations of compliance policies and/or any applicable regulation.

V. Offshore Contracting

Healthfirst is required to provide CMS with offshore subcontractor information and complete an attestation regarding protection of beneficiary Protected Health Information (PHI). Therefore, Healthfirst requires FDRs and Affiliates to indicate the name, address, and delegated function of any offshore subcontractors used for Healthfirst business.

CMS considers MA organizations, such as Healthfirst, to be a "contractor" with respect to CMS for the purposes of delivering Medicare Part C and Part D benefits. The term "subcontractor" refers to any organization that a sponsor contracts with to fulfill or help fulfill requirements in their Part C and/or Part D contracts. Subcontractors include all first tier, downstream, and/or related entities.

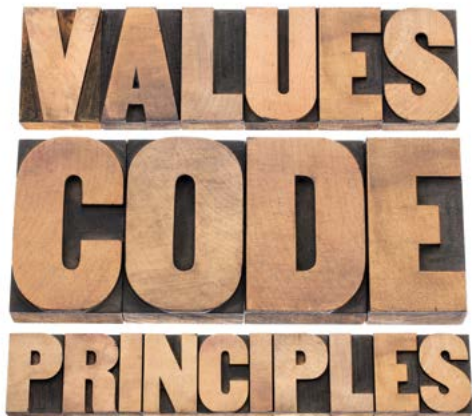


The term “offshore” refers to any country that is not one of the 50 United States or one of the United States Territories (American Samoa, Guam, Northern Marianas, Puerto Rico, and Virgin Islands). Examples of countries that meet the definition of “offshore” include Mexico, Canada, India, Germany, and Japan. Subcontractors that are considered offshore can be either American-owned companies with certain portions of their operations performed outside of the United States, or foreign-owned companies with their operations performed outside of the United States. Offshore subcontractors provide services that are performed by workers located in offshore countries, regardless of whether the workers are employees of American or foreign companies.

Section 3: The Healthfirst Code of Conduct

The Healthfirst Code of Conduct provides guidance to FDRs and Affiliates regarding the ethical and legal standards of our Compliance Program. We expect every FDR and Affiliate to respect these principles and to conduct business with Healthfirst in accordance with them. Failure to follow the Code of Conduct may lead to termination of a contract and relationship with Healthfirst. You can find the Healthfirst Code of Conduct here:

<https://healthfirst.org/fraud-and-compliance/>



Section 4: Healthfirst’s Commitment to Compliance

Healthfirst has systems, policies, and procedures in place to detect, correct, prevent, and monitor issues of noncompliance.

Monitoring and Auditing

Healthfirst routinely monitors and periodically audits first tier entities to ensure compliant administration of the Medicare and Medicaid contracts as well as applicable laws and regulations. Each first tier entity is required to cooperate and participate in the monitoring and auditing activities. If a first tier entity performs its own audits, Healthfirst may request the audit results affecting Healthfirst business. In addition, first tier entities are expected to routinely monitor and periodically audit their downstream entities.

If Healthfirst determines that an FDR or Affiliate is not in compliance with any of the requirements set forth in this policy, the FDR or Affiliate will be required to develop and submit a Corrective Action Plan (CAP). Healthfirst will assist the FDR or Affiliate in addressing the issues identified.

All monitoring and auditing activities must be documented and retained for a 10-year period. Healthfirst may require evidence of monitoring and auditing for future oversight and/or auditing purposes.

Healthfirst Investigations

It is Healthfirst’s policy to thoroughly and objectively investigate any specific allegation of misconduct, fraud, or abuse involving Healthfirst employees, accounts, or operations. Healthfirst holds individuals responsible for violations of Healthfirst’s policies, breaches of ethical behavior, or illegal acts committed against Healthfirst, on Healthfirst’s behalf, on Healthfirst premises, or during hours of, or within the scope of, Healthfirst business

operations (“Misconduct”). The reporting source of any allegation of wrongdoing, whether via the Healthfirst hotline, an email, telephone, in-person report, or any other source, is irrelevant to Healthfirst’s obligation to investigate. Healthfirst will conduct all investigations in a manner that protects the rights of those who may be the subject of allegations of wrongdoing, as well as the rights of those who, in good faith, make such allegations.

Healthfirst requires the cooperation of FDRs and Affiliates during any investigations that may involve (directly or indirectly) their organization or individuals associated with their organization. The investigation will be initiated by a representative of Healthfirst and continue until the investigation is completed. Coordination of investigations which involve any regulatory agency will be handled in accordance with their requests.

Healthfirst is required to refer potential fraud or misconduct related to the Medicare program to the HHS-OIG and the Medicare Drug Integrity Contractor (MEDIC) for fraud and misconduct related to the Medicare Prescription Drug Program. Potential fraud, waste, and abuse related to the NY State-funded programs are reported to the New York State Office of the Medicaid Inspector General (OMIG).

Non-Retaliation and Non-Intimidation

Healthfirst is committed to a culture that promotes the prevention, detection, investigation, and remediation of violations of the Healthfirst Code of Conduct, as well as all applicable laws including NYS Labor Law Sections 740 and 741, and Part 422 – Medicare Advantage Program: Subpart K, §422.503. To support this culture, Healthfirst has established a strict non-retaliation and non-intimidation policy to protect employees, FDRs, and Affiliates who, in good faith, report known or suspected misconduct, fraud, waste, and/or abuse. Each FDR and Affiliate must adopt a policy of non-retaliation and non-intimidation and publicize the policy to all employees and contractors.

Section 5: Fraud, Waste, and Abuse

What is Fraud, Waste, and Abuse?

Fraud: An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to themselves or another person. It includes any act that constitutes fraud under applicable federal or state law.

Waste: The extravagant, careless, or needless expenditure of funds resulting from deficient practices, systems, controls, or decisions.

Abuse: Practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards of care. It includes enrollee practices that result in unnecessary cost.



Common Methods of Fraud, Waste, and Abuse

- **Fabrication of Claims:** In the outright fabrication of claims or portions of claims, a fraud perpetrator uses legitimate patient names and insurance information either to concoct entirely fictitious claims or to add fictitious charges for treatments or services that were never provided or performed to otherwise legitimate claims.
- **Falsification of Claims:** In the falsification of claims, the perpetrator makes a material and intentional misrepresentation of one or more elements of information in the claim, for the purpose of obtaining a payment to which they are not entitled.
- **Unbundling:** Provider submits a claim reporting comprehensive procedure code (e.g., Resection of small intestine) along with multiple incidental procedure codes (e.g., Exploration of abdominal and Exploration of the abdomen) that are an inherent part of performing the comprehensive procedure. Some providers may submit the unbundled procedures on multiple claims in an attempt to bypass bundling edits in the claims-processing system.
- **Fragmentation:** Provider submits a claim with all the incidental codes or itemizes the components of the procedures/services (Antepartum care, Vaginal delivery, and Obstetric care) which includes the three components. Some providers may submit the unbundled procedures on multiple claims in an attempt to bypass fragmentation edits in the claims-processing system.
- **Duplicate Claim Submissions:** Submitting claims for the same services and beneficiary under two Tax Identification Numbers to bypass duplicate claim edits in the claims-processing system.

- **Fictitious Providers:** There has been fraud where perpetrators obtain current membership information from operatives working in the billing offices of legitimate providers (usually hospitals) and submit claims, usually on the CMS 1500 claim form.



Indicators of Fraud

There are many indicators of fraud, which, if noticed, should be brought to the attention of Healthfirst. A list of the most common indicators is included below:

- Addition of services to bill
- Claims for more than one pharmacy for the same member in a short period of time
- Claims for non-emergency services on weekends and holidays
- Claims that have been handwritten or that contain changes made by hand
- Diagnosis inconsistent with age or sex
- Eligibility file date of birth does not match date of birth on claim (indication that an ID card has been shared)
- Impossible or unlikely services for age or sex
- Inconsistency between provider type and/or specialty and services rendered
- Inconsistency between services billed and medical history



- Indication that coinsurance has been waived (illegal)
- Large distance between providers and member location
- Provider advertisement for free services, drugs, supplies, or durable medical equipment
- Providers demanding immediate payment for claims
- Providers with more than a few lost or stolen checks
- Reluctance or failure to submit medical records when requested
- Submission of identical claims for more than one member or family member

Section 6: Relevant Laws and Regulations

Deficit Reduction Act

As a participant in the Medicaid Program, we must comply with the terms of the Deficit Reduction Act of 2005 (the "DRA"). The DRA, specifically Section 6033, entitled "Employee Education About False Claim Recovery," which was effective January 1, 2007, requires any organization that receives \$5 million or more in Federal Medicaid funds annually (including payments from managed care companies such as Healthfirst) to adopt a compliance program in accordance with Federal law and to inform its employees and any contractor or agent of the terms of the False Claims Act. Any organization that does not comply with the requirements may be denied Medicaid reimbursement. *You should carefully consult with your attorney to determine if you are subject to this requirement.*

False Claims Act

31 U.S.C. 3729 – 3733
P.L. 2007, Chapter 265 (as amended by
P.L. 2009, Chapter 265)

The federal government amended the False Claims Act (FCA) to make it a more effective tool. Using the False Claims Act, private citizens (i.e., whistleblowers) can help reduce fraud against the government. The act allows everyday people to bring suits against groups or other individuals that are defrauding the government through programs, agencies, or contracts (the act does not cover tax fraud).

For the purposes of this policy, "knowing and/or knowingly" means that a person, with respect to the information, has actual knowledge of the information; acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required.

The federal False Claims Act (FCA) applies when a company or person:

- knowingly presents (or causes to be presented) to the federal government a false or fraudulent claim for payment;
- knowingly uses (or causes to be used) a false record or statement to get a claim paid by the federal government;
- conspires with others to get a false or fraudulent claim paid by the federal government; and/or
- knowingly uses (or causes to be used) a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the federal government.



False Claims Act Penalties

Those who defraud the government can end up paying triple (or more than) the damage done to the government, or a fine for every false claim, in addition to the claimant's costs and attorneys' fees. These monetary fines are in addition to potential incarceration, revocation of licensures, and/or becoming an "excluded" individual, which prevents an individual from being employed in any job that receives monies from the Federal Government, the State Government, or both.

FCA: Whistleblower Protections

The False Claims Act allows everyday people to bring suits against organizations or individuals who are defrauding the government (but the act does not cover tax fraud). These individuals are commonly known as "whistleblowers." If the government moves forward with a case, the individual who brings the suit is generally entitled to receive a percentage of any recovered funds once a decision has been made. If the government decides not to pursue the case, then the individual must pursue the issue on their own. If successful, they would also be entitled to a percentage of any recovered funds.

Federal statutes and related State and Federal laws shield employees from retaliation for reporting illegal acts of employers. An employer cannot retaliate in any way, such as discharging, demoting, suspending, or harassing the whistleblower. If an employer does retaliate, the employee may be entitled to file a charge with a government agency, sue the employer, or both.

To report information about fraud, waste, or abuse involving Medicare or any other healthcare program involving only federal funds, call the toll-free hotline established by the federal Office of Inspector General in the U.S. Department of Health and Human Services. The hotline number is **1-800-HHS-TIPS (1-800-447-8477)**.

For more information about this hotline and about other ways to contact the Office of Inspector General, you can go to <https://oig.hhs.gov/fraud/report-fraud/index.asp>.



Stark Law

The Stark Law, with several separate provisions, governs physician self-referral for Medicare and Medicaid patients. Physician self-referral is the practice of a physician referring a patient to a medical facility in which they have a financial interest, be it ownership, investment, or a structured compensation arrangement.

The Omnibus Budget Reconciliation Act of 1989 also bars self-referrals for clinical laboratory services under the Medicare program.

The law included a series of exceptions to the ban in order to accommodate legitimate business arrangements. The Omnibus Budget Reconciliation Act of 1993 expanded the restriction to a range of additional health services and applied it to both Medicare and Medicaid. The Social Security Act prohibits physicians from referring Medicare patients for certain designated health services to an entity with which the physician, or a member of the physician's immediate family, has a financial relationship—unless an exception applies. It also prohibits an entity from presenting, or causing to be presented, a bill or claim to anyone for a health service furnished as a result of a prohibited referral.

Violations of the Stark Law and the practice of physician self-referral are to be reported to the Centers for Medicare and Medicaid Services via its self-disclosure process.

Anti-Kickback Statute

The Medicare and Medicaid Patient Protection Act of 1987 provides the basis for this statute. It provides for criminal penalties for certain acts which impact Medicare and Medicaid or any other federally funded or State-funded program. If you solicit or receive any remuneration in return for referring an individual to a person (doctor, hospital, or provider) for a service for which payment may be made, it can be seen as a potential kickback. Remuneration includes payment, monies, or any goods or services from any healthcare facilities, programs, or providers.

Federal Program Fraud Civil Remedies Act

31 U.S.C. 3801-3812

For a copy of this citation, please visit:
<https://www.federalregister.gov/articles/2009/06/04/E9-12170/program-fraud-civil-remedies-act>

This act provides federal administrative remedies for false claims and statements, including those made to federally funded healthcare programs. Current civil penalties are \$5,000 for each false claim or statement, and an assessment in lieu of damages sustained by the federal government of up to double damages for each false claim for which the government makes a payment. The amount of the false claims penalty is to be adjusted periodically for inflation in accordance with a federal formula.



Section 7: Health Insurance Portability and Accountability Act (HIPAA)

HIPAA Privacy

The HIPAA Privacy Rule requires providers to take reasonable steps to protect and safeguard the Protected Health Information (PHI) of members/patients. A member's PHI is subject to the protections established by the Privacy Rule and under the contractual relationship between Healthfirst and the member, and between Healthfirst and the provider or FDR. PHI includes information regarding enrollment with Healthfirst, medical records, claims submitted for payment, etc. Such PHI must be safeguarded and held in strict confidence, so as to comply with applicable privacy provisions of State and Federal laws, including the Health Insurance Portability and Accountability Act (HIPAA). Ways in which a provider can protect member/patient PHI include ensuring that only authorized provider office employees have access to member/patient charts; including limited information on member/patient sign-in sheets; and restricting nonemployees from being in areas of the office that contain member/patient records.

HIPAA Security

The HIPAA Security Rule requires covered entities to adopt national standards for safeguards to protect the confidentiality, integrity, and availability of electronic protected health information (e-PHI) that is collected, maintained, used, or transmitted by a covered entity. As a covered entity, you must ensure that you have the appropriate administrative, technical, and physical safeguards in place to protect the data that is being electronically accessed by our workforce. You must (a) ensure the integrity and confidentiality

of the information; and (b) protect against any reasonably anticipated (i) threats or hazards to the security or integrity of the information; and (ii) unauthorized uses or disclosures of the information. This can be accomplished by establishing appropriate policies and procedures that outline your compliance with the Rule and your expectations of your workforce in complying with the Rule. Compliance with the Security Rule is not a one-time goal; it is an ongoing process that requires periodic risk analyses and audits of covered entities' employees' devices to confirm their compliance with your established policies.

A member's PHI must be safeguarded, and only those employees of the covered entity who have a business need to access the information should be permitted to do so. Access to member PHI should be role-based. This means that access should only be granted to a covered entity's employees based on their job duties and responsibilities within the organization.

Additional References

Healthfirst NY:
www.healthfirst.org

OIG Exclusion Database and Information:
<https://oig.hhs.gov/exclusions/index.asp>

U.S. Dept. of Health & Human Services:
www.hhs.gov/

NYS Office of the Medicaid
Inspector General:
<https://omig.ny.gov/>

Centers for Medicare & Medicaid Services:
<http://cms.gov/>





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