	Johns Hopkins HealthCare LLC Corporate and Medicare Compliance Departments	<i>Policy Number</i>	COR.018
		<i>Effective Date</i>	04/12/2012
		<i>Review Date</i>	10/08/18
	<u>Subject</u> Ongoing Monitoring for State and Federal Exclusion, Debarment and Sanctions	<i>Revision Date</i>	10/08/18
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This document applies to the following Participating Organizations:

- EHP ElderPlus Johns Hopkins Advantage MD Priority Partners
- US Family Health Plan

Keywords:

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I. ACTION


	New Policy	
	Repealed Policy Date	
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II. POLICY

The U.S. Department of Health and Human Services, Office of Inspector General, has the authority to exclude individuals and entities who have engaged in fraud and abuse from participation in Medicare, Medicaid, and other Federal Health Care Programs and to impose civil monetary penalties (“CMPs”) for certain misconduct related to Federal and State Health Care Programs. Exclusions are either mandatory or permissive: mandatory exclusions are required by law and permissive exclusions are imposed by the Office of Inspector General’s discretion. The effect of any exclusion is that no government-issued payment may be made for any items or services (1) furnished by an excluded individual or entity, or (2) directed or prescribed by an excluded physician. Anyone who hires or contracts with an individual or entity excluded by the Office of Inspector General may also be subject to CMPs. To avoid CMP liability, the Office of Inspector General recommends that health care entities screen new hires or contractors and current employees and contractors for such exclusion on a monthly basis.

The Centers for Medicare and Medicaid Services issued guidance to State Medicaid Agencies on January 16, 2009 that advises States of their obligation to direct providers to screen their employees and contractors for such exclusion to prevent Medicaid payments for items or services furnished or ordered by excluded individuals or entities. It further advises States to require providers to search the Office of Inspector General’s List of Excluded Individuals and Entities monthly to capture new exclusions or reinstatements that occurred since the last search.

Johns Hopkins HealthCare LLC (“JHHC”) and its Participating Organizations are committed to ensuring that all employees, medical staff, contractors, vendors and others providing administrative or health care services relating to Federal and State Health Care Programs with whom JHHC and its Participating Organizations do business with are properly screened for exclusions, debarment, and state sanctions and are authorized to participate in Federal and State Health Care Programs. Such screening involves diligent research on the U.S. Department of Health and Human Services-Office of the Inspector General’s

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List of Excluded Individuals and Entities, the General Services Administration's System for Award Management, and the Maryland Department of Health's Sanctioned Provider's List.

JHHC and its Participating Organizations will not employ or engage in a business relationship with anyone who is currently under exclusion, debarment, or sanction by the U. S. Department of Health and Human Services-Office of Inspector General, the Maryland Department of Health, and any other duly authorized enforcement agency or licensing and disciplining authority.

JHHC and its Participating Organizations will not employ any individuals who have been recently convicted of a criminal offense related to healthcare and will remove individuals with direct responsibility for or involvement with any Federal or State Health Care Program, as well as those pending the resolution of any criminal charges or proposed exclusion, debarment, or sanction.

III. SCOPE

This policy applies to personnel at JHHC and Johns Hopkins Health System ("JHHS"), an affiliate of JHHC, tasked with conducting screenings for the Participating Organization's new and current workforce members, Board of Directors, contractors, medical staff, vendors, and First Tier, Downstream, or Related Entities as defined in Appendix A.

The following are brief descriptions of the Participating Organizations impacted by this policy:


- **EHP:** a Third Party Administrator for Self-Insured Plans.
- **ElderPlus:** a Medicare PACE program designed to provide and coordinate all needed preventative, primary, acute, and long-term care services so that older individuals can continue living in the community.
- **Johns Hopkins Advantage MD:** a Medicare Advantage Organization ("MAO").
- **Priority Partners:** a Medicaid Managed Care Organization.
- **US Family Health Plan:** a managed care program developed by the Department of Defense that offers health care benefits to eligible beneficiaries of the uniformed services, including active-duty family members, retirees and their family members, and survivors.

IV. ABBREVIATIONS

- Centers for Medicare and Medicaid Services (CMS)
- Code of Federal Regulations (CFR)
- Code of Maryland Annotated Regulations (COMAR)
- Department of Health and Human Services (DHHS)
- General Services Administration (GSA)
- Health Insurance Portability and Accountability Act of 1996 (HIPAA)
- Maryland Department of Health (MDH)
- Office of Inspector General (OIG)
- Social Security Act (SSA)
- System Award Management (SAM)
- United States Code (USC)

V. KEY TERMS & DEFINITIONS

See Appendix A for a Glossary of Terms used in the content of this policy. All definitions used shall be deemed automatically updated as revisions to laws or regulations occur from time to time.

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VI. REQUIREMENTS, RESPONSIBILITIES & PROCEDURES

As part of an effective compliance program, HHS-OIG and CMS require Federal and State Health Care Programs to:

1. Not engage, employ, contract with, or pay claims to any individuals, including workforce members (including permanent, temporary, interns, and volunteers), Board members and/or attendees, providers, or contractors who are currently debarred, sanctioned, or mandatorily or permissively excluded from participation in Federal or State Health Care Programs or who have opted out of the Medicare program; and
2. Require all FDRs that provide administrative or health care services for Federal or State Health Care Programs to comply with all applicable laws and regulations.


In addition to the screening and monitoring requirements, all new and existing workforce members, Board members and attendees, and contractors must immediately disclose to the Participating Organization any debarment, exclusion, or any other event that makes them ineligible to perform work directly or indirectly related to Federal or State Health Care Programs.

A. Responsible Parties for Initial and Ongoing Monitoring

Appendix B outlines by type, all exclusionary/debarment/sanction checks performed by JHHC, on behalf of the Participating Organizations, in accordance with regulatory requirements.

B. Participating vs. Non-Participating - Federal and/or State Exclusions, Debarments, Sanctions, and Contract Violations

1. **Exclusions:**
If a Participating (PAR) Provider or Non-Participating (NON-PAR) Provider is excluded from any Federal Health Care Program, the Participating Organization may not pay the excluded provider using federal monies dating back to the date of the exclusion and continuing until reinstatement, unless the exception for Emergency Services applies. This prohibition applies to Johns Hopkins Advantage MD, Priority Partners, ElderPlus, and US Family Health Plan, respectively.
2. **Debarments:**
If a PAR or NON-PAR Provider is federally debarred, the Participating Organization may not pay the debarred provider through or with funds from any Federal Health Care Program dating back to the date of debarment and continuing until the debarred provider is no longer debarred. This prohibition applies to Johns Hopkins Advantage MD, Priority Partners, ElderPlus, and US Family Health Plan, respectively.
3. **State Sanctions:**
If a PAR or NON-PAR Provider is sanctioned on the Maryland Department of Health's Sanctioned Provider's List, the Participating Organization may not pay the sanctioned provider through or with funds from any Federal or State Health Care Program dating back to the date of the sanction and continuing until the sanctioned provider is no longer sanctioned. This prohibition applies to Johns Hopkins Advantage MD, Priority Partners, ElderPlus, and US Family Health Plan, respectively.
4. **License Board Sanction:**
 - a. A PAR or NON-PAR Provider whose state license is suspended, expired, or revoked will not be reimbursed for any items or services dating back to the date of the suspension and continuing until such suspension is lifted.
 - b. A PAR or NON-PAR Provider with US Family Health Plan whose license is active but restricted (not at the full clinical level of practice) will not be reimbursed for any items of services dating back to the date of the restriction

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and continuing until such restriction is lifted. Any other PAR or NON-PAR Provider whose state license is active but placed on restriction may be reimbursed.¹

5. Contract violations:

Exclusion, debarment, state sanctions, and license board sanctions each result in the Par Provider's breach of the provider contract with the Participating Organization. As such, the providers in breach of their contract may not be paid through or with funds from any Federal or State Health Care Program dating back to the date of exclusion, debarment, state sanction, or license board sanction and continuing until the action is resolved.

C. Termination of Providers/Entities and/or FDRs Found to be Excluded, Debarred, Sanctioned, or Without Valid Licensure

1. Providers/entities

- a. The Credentialing Department will immediately terminate excluded, debarred, sanctioned, or unlicensed providers or entities from all of the networks of the Participating Organizations.
- b. The Provider Maintenance Department will annotate the claim system concerning the Participating Organization's inability to pay said provider.
- c. The Participating Organization's delegated party responsible for credentialing must terminate its JHHC contract with any excluded, debarred, sanctioned, or unlicensed providers/entities.

2. FDRs

- a. For MAOs, generally, the Vice President of Medicare Advantage will terminate the MAO's relationship with such FDRs found to be excluded, debarred, or without valid licensure; and
- b. For all other Participating Organizations, the appropriate senior level management will be notified and appropriate action will be taken.


D. Recoupment of Any and All Errant Participating Organization Payments

1. If payment is made to an excluded, debarred, sanctioned, or unlicensed individual or entity, the Compliance Director will:

- a. Review the Participating Organization's contract with the provider to determine whether the contract is with an individual provider or with a group provider.
- b. Send a notification letter to the provider and/or group notifying the recipient of the determination.
- c. If the Department does not receive a timely response from the affected provider and/or group (i.e., within five calendar days of the notice), the Director will forward the case to the Manager of COB for placement in collections.
- d. All written communication is to occur by a trackable method.

2. Use of Futures

- a. No provider/entity who is excluded, debarred, sanctioned, or unlicensed should be placed in futures as there cannot be future billings or future claims to offset for return to the appropriate Participating Organization.
- b. Exceptions:
 - i. If the Participating Organization's contract is with a provider group that the excluded provider is a member of, the Compliance Director will send its correspondence to the group and not the individual provider since it is the group that is being reimbursed and not the individual provider. If the group fails to make payment, the group will be placed into futures until the repayment obligation is satisfied. Use of futures is not a condition of

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collections such that the group may be placed immediately into collections, at the Participating Organization's sole discretion.

- ii. If the Participating Organization's contract is with a single provider and the provider has IBNR (incurred but not reported) claims for a period prior to exclusion, debarment, or sanction, the provider will be placed in futures, until the repayment obligation is satisfied. Use of futures is not a condition of collections such that the provider may be placed immediately into collections, at the Participating Organization's sole discretion.

E. **Attestation**

Annually, Participating Organizations may require FDRs and contractors to sign an attestation signifying their compliance with exclusion/debarment monitoring and its willingness/ability to provide proof of said monitoring upon request by either the Participating Organization, CMS, or the State of Maryland (or their designees) as applicable. Monitoring includes the First Tier Entity's employees, and its Downstream and Related Entities.

1. Annually, as part of its ongoing monitoring efforts, the MAO will pull a random sample across all FDR types to assess the provider/entity(ies) compliance with this standard.
2. Any FDR not in compliance with this standard will be immediately re-educated, required to demonstrate proof (within three (3) business days) of entire workforce member screening, imposition of a corrective action plan (which includes monthly ongoing monitoring by the Compliance Department), and referral to the FDR Oversight Committee for potential further disciplinary action.

F. **Reporting**


Results of the Compliance Departments' ongoing monitoring of the MAOs and its FDRs exclusionary/debarment activities will be reported monthly to the Medicare FDR Oversight Committee, quarterly to the appropriate Compliance Oversight Committee, and semi-annually to the appropriate Board.

G. **Storage and Retrieval of Data**

All ongoing monitoring results will be stored electronically for ten (10) years. All documents will be retrievable and be made available for audit upon request for audit by CMS or its designee.

VII. REFERENCES

- Social Security Act §1128: Exclusion of Certain Individuals and Entities from Participation in Medicare and State Health Care Programs
- 42 CFR 1001: Program Integrity – Medicare and State Health Care Programs
- 42 USC 1320a-7: Criminal Penalties for Acts Involving Federal Health Care Programs
- HHS-OIG Special Advisory Bulletin on the Effect of Exclusion from Participation in federal Health Care Programs (2013).
- 42 CFR Part 422: Medicare Advantage Program
- 42 CFR Part 423: Voluntary Medicare Drug Benefit
- 42 CFR 438.610: Managed Care: Additional Program Integrity Safeguards: Prohibited Affiliations
- COMAR 10.09.64.03: Maryland Medicaid Managed Care Program: MCO Application: Organization, Operations, and Financing
- Title XVIII of the Social Security Act: Health Insurance for the Aged and Disables
- Title XIX of the Social Security Act: Grants to States for Medical Assistance Programs
- Executive Order 12549 Debarment and Suspension; 13 CFR 400.109 – Government-wide Debarment and Suspension (non-procurement).

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- 32 CFR 199.9 (f): Administrative Remedies for Fraud, Abuse and Conflict of Interest
- 31 USC 3729: Federal False Claims Act
- MD Code, General Provisions, Title 8: Maryland State False Claims Act
- Medicare Managed Care Manual, Chapter 6: Relationships with Providers
- Medicare Prescription Drug Benefit Manual
- MAPD Policies and their associated Compliance Department workflows and procedures related to:
 - Risk Assessment
 - Special Investigation Unit Investigation, Corrective Action Assignment and Monitoring
 - Annual Audit Work Plan
 - FDR Oversight Committee
 - Hopkins Health Advantage Compliance Oversight Committee
- JHHC Credentialing Policy PCR 002
- TRICARE Operations Manual Chapter 13 Sections 6 and 7
- TRICARE Policy Manual Chapter 11 Section 3.2

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Appendix A: Glossary of Terms

Conviction of a criminal offense is:

1. When a judgment of conviction has been entered against the individual or entity by a Federal, State, or local court, regardless of whether there is an appeal pending or whether the judgment of conviction or other record relating to the criminal conviction has been expunged;
2. When there is a finding of guilt against the individual or entity by a Federal, State, or local court;
3. When a plea of guilty or nolo contendere by the individual or entity has been accepted by a Federal, State, or local court; or
4. When the individual or entity has entered into participation in a first offender, deferred adjudication, or other arrangement or program where judgment of conviction has been withheld.

Debarment is an action taken by a Federal agency to prohibit a recipient from participating in Federal Government procurement contracts and covered non-procurement programs. Debarment is published on the SAM, a GSA administered website.

Downstream Entity is any entity that enters into a written arrangement below the level of the arrangement between a sponsor and a First Tier Entity for the provision of administrative services or health care services to a Medicare eligible individual under the Medicare Advantage program or Part D program (e.g., hospitals, providers, billing companies).

Effective Date of and Period of Exclusion, also known as **Reinstatement**, are defined as:

1. An exclusion under section 1128 or under section 1128A of the SSA will be effective at such time and upon such reasonable notice to the public and to the individual or entity excluded as may be specified in regulations.
2. Exclusion will be effective with respect to services furnished to an individual on or after the effective date of the exclusion.
 - a. Exceptions:
 - i. Unless the Secretary determines that the health and safety of individuals receiving services warrants the exclusion taking effect earlier, an exclusion will not apply to payments made under Title XVIII or under a State Health Care Program for:
 - Inpatient institutional services furnished to an individual who was admitted to such institution before the date of the exclusion, or
 - Home health services and hospice care furnished to an individual under a plan of care established before the date of the exclusion, until the passage of 30 days after the effective date of the exclusion.
3. An individual or entity excluded (or directed to be excluded) from participation under section 1128A of the SSA may apply to the Secretary, at the end of the minimum period of exclusion provided for termination of the exclusion.
 - a. The Secretary may terminate the exclusion if the Secretary determines, on the basis of the conduct of the applicant which occurred after the date of the notice of exclusion or which was unknown to the Secretary at the time of the exclusion, that –
 - i. There is no basis for a continuation of the exclusion, and
 - ii. There are reasonable assurances that the types of actions which formed the basis for the original exclusion have not recurred and will not recur.
 - b. The Secretary will promptly notify each appropriate State agency administering or supervising the administration of each State Health Care Program of the fact and circumstances of each termination of exclusion made under this subsection.

Emergency Services is defined under both Federal and State law.

1. Under Federal law, per 42 C.F.R. §1001.1901(c)(5), “emergency services” is an exception to the normal freezing effect of exclusion on payment for services. As such, payment may be made under Medicare, Medicaid, or other Federal Health Care Programs for certain emergency items or services furnished by an excluded individual or entity, or at the medical direction or on the prescription of an excluded physician or other authorized individual during the period of exclusion. To be payable, a claim for such emergency items or services must be accompanied by a sworn statement of the person furnishing the items or services specifying the nature of the emergency and why the items or services could not have been furnished by an individual or entity eligible to furnish or order such items or services. Notwithstanding this, no claim for emergency items or services will be payable if such items or services were provided by an excluded individual who, through an employment, contractual or any other arrangement, routinely provides emergency health care items or services.
2. Under State law, per COMAR 10.09.36.01, “emergency services” means those services which are provided in hospital emergency facilities after the onset of a medical condition manifesting itself by symptoms of sufficient severity that the absence of immediate medical attention could reasonably be expected by a prudent layperson, possessing an average knowledge of health and medicine, to result in:
 - a. Placing health in jeopardy;
 - b. Serious impairment to bodily functions;
 - c. Serious dysfunction of any bodily organ or part; or
 - d. Development or continuance of severe pain.

FDRs are First Tier, Downstream, and Related Entities.

Federal Health Care Program is defined as any plan or program that provides health benefits, whether directly, through insurance, or otherwise, and that is funded directly, in whole or in part, by the United States Government or a State Health Care Program (except for the federal Employees Health Benefits Program). Among the most significant Federal Health Care Programs are Medicare, Medicaid, TRICARE, and the veterans’ programs.

Federal Mandatory Exclusion. Per section 1128 of the SSA, the Secretary of DHHS will exclude the following individuals and entities from participation in any Federal Health Care Program:

1. Conviction of program-related crimes.—Any individual or entity that has been convicted of a criminal offense related to the delivery of an item or service under Title XVIII of the SSA or under any State Health Care Program.
2. Conviction relating to patient abuse.—Any individual or entity that has been convicted, under Federal or State law, of a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service.
3. Felony conviction relating to health care fraud.—Any individual or entity that has been convicted for an offense which occurred after the date of the enactment of HIPAA, under Federal or State law, in connection with the delivery of a health care item or service or with respect to any act or omission in a health care program (other than those specifically described in paragraph (1)) operated by or financed in whole or in part by any Federal, State, or local government agency, of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.
4. Felony conviction relating to controlled substance.—Any individual or entity that has been convicted for an offense which occurred after the date of the enactment of HIPAA, under Federal or State law, of a criminal offense consisting of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

First Tier Entity is any party that enters into a written arrangement with a Medicare Advantage Organization (“MAO”) or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare eligible individual under the Medicare Advantage (“MA”) program or Part D program (e.g., independent practice association, pharmacy benefit manager, credentialing entities).

List of Excluded Individuals and Entities (“LEIE”) is a list of excluded individuals and entities published and maintained by DHS-OIG. The OIG has the authority to exclude individuals and entities from Federal Health Care Programs pursuant to section 1128 and section 1156 of the SSA. The effect of an OIG exclusion from Federal Health Care Programs is that no Federal Health Care Program payment may be made for items or services furnished by an excluded individual or entity, or directed or prescribed by an excluded physician. Anyone who hires an individual or entity on the LEIE may be subject to civil monetary penalties (“CMP”). To avoid CMP liability, health care entities must routinely check the LEIE to ensure that new hires and current employees are not on the excluded list. The OIG recommends a monthly check.

Medicare Advantage Plan, (“Plan”, “MA organization” “MAO” or “Plan Sponsor”), for purposes of this policy, is defined as the Hopkins Health Advantage, Inc. Managed Medicare Part C and Part D Prescription Drug Benefit offerings. In Chapter 1 of the Managed Medicare Manual, CMS defines a MA Plan - Health benefits coverage offered under a policy or contract by an MA organization that includes a specific package of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area (or segment of the service area) of the MA Plan.

Permissive Exclusion. Per section 1128 of the SSA, the Secretary of DHHS may exclude the following individuals and entities from participation in any Federal Health Care Program:

1. Conviction relating to fraud.
2. Conviction relating to obstruction of an investigation or audit.
3. Misdemeanor conviction relating to controlled substance. – Any individual or entity that has been convicted, under Federal or State law, of a criminal offense consisting of a misdemeanor relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.
4. License revocation or suspension. – Any individual or entity:
 - a. Whose license to provide health care has been revoked or suspended by any State licensing authority, or who otherwise lost such a license or the right to apply for or renew such a license, for reasons bearing on the individual’s or entity’s professional competence, professional performance, or financial integrity, or
 - b. Who surrendered such a license while a formal disciplinary proceeding was pending before such an authority and the proceeding concerned the individual’s or entity’s professional competence, professional performance, or financial integrity.
5. Exclusion or suspension under Federal or State Health Care Program. – Any individual or entity which has been suspended or excluded from participation, or otherwise sanctioned, under—
 - a. Any Federal program, including programs of the Department of Defense or the Department of Veterans Affairs, involving the provision of health care, or
 - b. A State health care program, for reasons bearing on the individual’s or entity’s professional competence, professional performance, or financial integrity.
6. Claims for excessive charges or unnecessary services and failure of certain organizations to furnish medically necessary services.—Any individual or entity that the Secretary of DHHS determines –
 - a. Has submitted or caused to be submitted bills or requests for payment (where such bills or requests are based on charges or cost) under Title XVIII of the SSA or a State Health Care Program containing charges (or, in applicable cases, requests for payment of costs) for items or services furnished substantially in excess of such individual’s or entity’s usual charges (or, in applicable cases, substantially in excess of such individual’s or entity’s costs) for such items or services, unless the Secretary finds there is good cause for such bills or requests containing such charges or costs;
 - b. Has furnished or caused to be furnished items or services to patients (whether or not eligible for benefits under Title XVIII or under a State Health Care Program) substantially in excess of the needs of such patients or of a quality which fails to meet professionally recognized standards of health care;
 - c. Is –
 - i. A health maintenance organization (as defined in section 1903(m) of the SSA) providing items and services under a State plan approved under Title XIX, or
 - ii. An entity furnishing services under a waiver approved under section 1915(b)(1) of the SSA, and has failed substantially to provide medically necessary items and services that are required (under law or the contract with the State under Title XIX) to be provided to individuals covered under that plan or waiver, if the failure has adversely affected (or has a substantial likelihood of adversely affecting) these individuals; or

- d. Is an entity providing items and services as an eligible organization under a risk-sharing contract under section 1876 of the SSA and has failed substantially to provide medically necessary items and services that are required (under law or such contract) to be provided to individuals covered under the risk-sharing contract, if the failure has adversely affected (or has a substantial likelihood of adversely affecting) these individuals.
7. Fraud, kickbacks, and other prohibited activities.—Any individual or entity that the Secretary determines has committed an act which is described in section 1128A, 1128B, or 1129 of the SSA.
8. Entities controlled by an individual sanctioned by the Secretary of DHHS.
9. Failure to disclose required information – any entity that did not fully and accurately make any disclosure required by section 1124, section 1124A, or section 1126 of the SSA.

Related Entity is any entity that is related to an MAO or Part D sponsor by common ownership or control and either:

1. Performs some of the MAO 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 an MAO or Part D plan sponsor at a cost of more than \$2,500 during a contract period.

State Health Care Program is defined as:

1. A State plan approved under Title XIX of the SSA,
2. Any program receiving funds under Title V of the SSA or from an allotment to a State under such title,
3. Any program receiving funds under Subtitle I of Title XX of the SSA or from an allotment to a State under such subtitle, or
4. A State child health plan approved under Title XXI of the SSA.

System for Award Management (“SAM”) is the current Official U.S. Government system, maintained by the GSA, consolidated the capabilities and functionality of multiple systems used by the Federal government. While the LEIE contains exclusion actions taken by the OIG, SAM provides a single, comprehensive sanctions list of individuals and entities excluded by a variety of Federal government agencies from receiving federal contracts or federally approved subcontracts and from certain types of federal financial and nonfinancial assistance and benefits.

Workforce members, for purposes of this policy only, are persons under the direct control of Johns Hopkins Health System or Johns Hopkins Healthcare, including, but not limited to, employees, students, interns, staff, faculty, volunteers, and temporary personnel.