

Sanction, Exclusion, Preclusion and Medicare Opt Out Review Policy

Policy Number: A20130905076

Effective Date: 9/1/2013

Sponsoring Department: Compliance

Impacted Department(s): All Independent Health, and its affiliated organizations (Nova, Reliance Rx, PBD, WNY Collaborative Management Services LLC)

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐ Confidential ☒ Restricted ☐ Public

Applies to (Line of Business):

- ☐ Corporate (All)
- ☒ State Products, if yes which plan(s): ☒ MediSource; ☒ MediSource Connect; ☒ Child Health Plus; ☒ Essential Plan
- ☒ Medicare, if yes, which plan(s): ☒ MAPD; ☒ PDP; ☒ ISNP; ☒ CSNP
- ☒ Commercial, if yes, which type: ☐ Large Group; ☒ Small Group; ☒ Individual
- ☐ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☒ No ☐

Purpose and Applicability:

To require systematic monitoring of the following eight sanction and exclusion lists as required by state and federal contracts:

- 1) the Office of the Inspector General (OIG) List of Excluded Individuals and Entities (LEIE);
- 2) the System for Award Management (SAM) Exclusions formerly the Excluded Parties List Service (EPLS);

- 3) the New York Office of Medicaid Inspector General (OMIG) list of excluded Providers and Entities;
- 4) New York Medicare Opt Out;
- 5) the U.S. Treasury's Office of Foreign Assets Control's (OFAC) List of Specially Designated Nationals and Blocked Persons (list of blocked persons) in compliance with the Presidential Executive Order on Terrorist Financing Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism;
- 6) OPM's Office of the Inspector General's Guidance for the Implementation of Federal Employees Health Benefits Program (FEHBP) Debarment and Suspension Orders;
- 7) New York State Office of General Services - Iran Divestment Act; and
- 8) Federal Preclusion List.

And to require reviews, as necessary, of the following lists as required by state and federal contracts:

- 1) The Social Security Administration's Death Master File (DMF).

This monitoring is intended to identify and follow-up on any sanctioned individuals who might be associated with Independent Health and/or its subsidiaries to prevent fraud and prohibited payments. In addition to the monitoring, workforce members are required to immediately disclose to the Compliance Officer (or designee) if they become an **Ineligible Person**.

Policy:

Independent Health will not make payments to any individual or entity, including but not limited to providers, prescribers, **vendor**, and/ or **workforce member**, who are **ineligible** and included on any of the eight aforementioned lists. In addition, Independent Health will provide timely notification to beneficiaries who received services from a sanctioned, excluded, opted out, and/or precluded provider in accordance with CMS, DOH, OMIG and/or OFAC deadlines. Independent Health will take action to remove sanctioned, excluded, opted-out and/or precluded providers, including precluded pharmacies, from any/all applicable networks. The failure of any workforce member to disclose any sanctions, exclusions or preclusions may result in disciplinary action up to and including termination of employment.

Independent Health is responsible for obtaining and reviewing the eight aforementioned lists at least monthly and prior to new hire/new contracting, as appropriate, against internal lists of:

- Current associates of Independent Health and its subsidiaries;
- Contingent workers including vendors and consultants
- Boards of Directors of IHA, IHC, IPA, and IHBC;
- Committee Members of Pharmacy and Therapeutics (P&T), Contractual, Clinical, Peer Review Quality
- Currently contracted (or participating) providers
- Current prescribers;
- Provider applicants;
- Members; and
- State-wide non-participating providers for which claims may be processed.

And, as necessary, review the Social Security Administration's Death Master File (DMF) list per the Credentialing process.

Independent Health requires contracted vendor partners to also maintain a process of ensuring that all entities (i.e. employees and subcontracted downstream entities) are reviewed monthly and prior to hire or contracting. Independent Health maintains the right to monitor and/or audit this process to ensure compliance with all regulatory requirements. Please refer to the **Compliance Program FDR and Management Contractor Oversight Policy # A20140128003**.

The Compliance area oversees the sanction, exclusion, opt-out and preclusion list review processes involving the following departments: Product Operations, Network Contract Management, Sales, Finance, Enrollment, Pharmacy, Human Resources, Legal, Credentialing, Claims and SIU.

If a potential match is identified during the exclusion list process, such information, when appropriate, is forwarded to the Special Investigation Unit (SIU) to determine if the potential match should be reported to OFAC or one of the other regulatory entities as required or blocked from further payment mechanisms. The potential consequences of lack of identification and follow-up of associates, contingent workers, agents and persons with ownership or control interests whose names appear on the OIG Sanction Report or other excluded entity lists are serious and may result in immediate termination or removal. The Office of the Inspector General must be notified in writing within 30 days of identifying an ineligible person.

Upon confirmation of any criminal convictions by providers and/or managing associates / contingent workers related to Medicare, Medicaid, or Title XX programs, Independent Health must notify the Department of Health within 20 days, pursuant to 42 CFR §455.105 and 42 CFR §455.106. Such reviews will be completed upon entering into an initial application, agreement, or renewal of any agreement between the contracted vendor and its Providers. Additionally, any payments recovered from providers that have been excluded from the Medicaid program will be reported within 60 days of being identified pursuant to the Medicaid Model Contract Section 21.5(c).

All **workforce members** must immediately disclose to the Compliance Officer if they become an **ineligible person**. Failure to disclose an individual or entities ineligibility status, or failure to follow up on known excluded persons and/or entities will be a violation of this policy and may result in disciplinary action up to and including termination. Please refer to the Progressive Discipline Policy #A040628200.

Pre-Authorization Required? Yes ☐ No ☐

Definitions

Contingent workers: are external resources, not employed by **Independent Health** which include: Temporaries (including interns), Consultants, Contractors, **Vendors**, Board Members, and cloud users.

FDR:

- **Downstream Entity** means any party that enters into a written arrangement acceptable to CMS, below the level of the arrangement between Independent Health and a first-tier entity.
- **First Tier Entity** means any party that enters into a written arrangement acceptable to CMS with Independent Health.
- **Related Entity** means any entity that is related to Independent Health by common ownership or control and:
 1. Performs some of the Independent Health's management functions under contract or delegation; or
 2. Furnishes services to Medicare enrollees under an oral or written agreement; or
 3. Leases real property or sells materials to Independent Health at a cost of more than \$2,500 during a contract period.

Independent Health means Independent Health Association, Inc., its affiliates, and subsidiaries or 'family of companies'.

Ineligible Person means an individual or entity who: (a) is currently excluded from participation in any Federal health care program or (b) has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a) (mandatory exclusion) but has not yet been excluded from participation in any Federal health care program.

Out-of-area associates: Business needs may necessitate the employment of associates who work and reside out of the state of the company's principal place of business; designated as "remote" in workday. (Established under the requirements outlined in the alternate work arrangements policy.)

Preclusion List: a list of providers, including prescribers, who are currently revoked from Medicare, or who have engaged in conduct which would have led to a revocation if the provider had been enrolled in Medicare at the time the conduct occurred. The actions of these providers are deemed "detrimental to the best interests of the Medicare program."

Subcontractor/subcontracted: any organization that **Independent Health** contracts with to fulfill or help fulfill requirements in its Medicare (Part C and/or Part D) contracts, Medicaid Managed Care and Family Health Plus Model contracts, Qualified Health Plan contract, and any other legally binding agreement. Additionally, this term could also refer to one of Independent Health's direct subcontractors, that then itself subcontracts work or services to yet another entity.

Vendor: any business, entity, or person that **Independent Health** enters into a written arrangement (or similar agreement) to provide administrative, consultative, health care, data storage, and application development services. A vendor could also be a: a) delegated and/or a **First Tier and Downstream (FDR) entity**, b) a Business Associate, and/or c) a **Subcontractor** (see definitions above).

Workforce members: includes associates of **Independent Health**, its family of companies (full or part time, including **out of area associates**), and applicable **contingent workers**, including governing body members, in addition employees of **vendors** that directly support operational, administrative or health care services for **Independent Health**.

References

Related Policies, Processes and Other Documents

- Mechanisms for Reporting/Disclosing Noncompliance and Corrective Action Policy (A990801007)
- Compliance Reporting/Disclosure Response SOP
- Background Check Policy, Policy # A20120404003
- Corrective Action/Progressive Discipline Policy, Policy # A040628200
- Compliance, Privacy and Security Event Scoring Policy, Policy #A20140303001
- Compliance Program FDR and Management Contractor Oversight Policy, Policy # A20140128003
- Offshore Contracting Policy, Policy # A110418118
- Adverse Action Notification Policy, Policy # M000101147
- Monitoring of Practitioner and Provider Sanctions, Licensure, Medicare Status, and Complaints, Policy # M020904436
- Mechanisms for Reporting/Disclosing Noncompliance and Corrective Action Policy (A990801007)
- Compliance Reporting/Disclosure Response SOP
- Exclusion List Review and Reporting Process - Compliance
- New Vendor WatchDog Review Process - Compliance
- Exclusion/Preclusion List, Opt-Out and Termed Provider Process – Special Investigations Unit (SIU)
- WatchDog SOP – Finance
- Watchdog Procedures- Pharmacy
- Sanction Process – WatchDOG – Human Resources
- Monitoring of Practitioners/Provider Sanctions, Licensure, Medicare Status, and Complaints Process - Credentialing
- Adverse Action Notification Process—Credentialing
- Business Process Identifying Medicare Opt Out Providers – Network Contract Management
- Standard Operating Process CSI WATCHDOG – Network Contract Management
- 37 Review – Medicare Opt Out– Claims
- WatchDog Provider Sanction Process – Claims
- Opt Out Provider Process- Medicare- Benefit Administration

Regulatory References

- Social Security Act, §1128, §1156, §1862(e)(1)(B), §1892
- 42 U.S.C. §1320a–7a
- 42 CFR §422.204(b)(4)
- 42 CFR §422.220
- 42 CFR §422.752(a)(8)
- 42 CFR §423.752(a)(8)
- 42 CFR §498
- 42 CFR §405.415
- 42 CFR §405.435
- 42 CFR §405.440
- 42 CFR §417
- 42 CFR §422.220
- 42 CFR §498.3(b)
- 42 CFR §455.105
- 42 CFR §455.106
- 42 CFR §455.436
- 42 CFR §1001.1901

- Medicare Managed Care Manual, Chapter 6, §60.2
- Medicare Managed Care Manual, Chapter 21/Medicare Prescription Drug Manual, Chapter 9, §50.6.8
- Medicare Benefit Policy Manual, Chapter 15, §40.6, §40.7, §40.8, §40.9, §40.11, §40.12, §40.28
- Medicare Claims Processing Manual, Chapter 1, §30.2.13
- Medicaid Managed Care Contract Section 18.9, Section 18.12 (a)&(b), Section 21.5
- Executive Order 13224 – Presidential Executive Order on Terrorist Financing Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism (66 Fed. Reg. 49079 (2001))
- Federal Financial Crimes Enforcement Network’s Final Rules re Patriot Act
- New York State Iran Divestment Act of 2012
- Office of Personnel Management’s Inspector General’s FEHBP Administrative Sanctions, which also includes the following references:
 - Federal Employees Health Care Protection Act of 1998;3
 - Government wide Non-procurement Debarment and Suspension Common Rule (68 FR 66533)
 - Title 5, Code of Federal Regulations, Part 890, Subpart J (5 CFR 890)
 - Title 5 of the U.S. Code, Part III, Subpart G, Chapter 89 (5 USC 8902a).
- Public Law No: 114-10 (04/16/2015) H.R.2 – Medicare Access and CHIP Reauthorization Act of 2015 - Section 106 (amends section 1802(b)(3) of the Act to require that opt-out affidavits filed on or after June 16, 2015, automatically renew every 2 years)
- Invitation and Requirements for Insurer Certification and Recertification for Participation in 2024: Qualified Health Plans, Stand-Alone Dental Plans & Essential Plans, Section 4 (C)(3)
- CMS letter dated 11/2/18 on Preclusion List requirements
- CMS Frequently Asked Questions on the Preclusion List requirements
- HPMS Memo dated 2/19/19 on Updates to the Drug Data Processing System (DDPS)

Version Control

Sponsored By:

Name sponsor: Nicole Britton

Title of sponsor: VP-Chief Compliance Officer

Signature of sponsor:



Revision Date	Owner	Notes
9/1/2013	D. Odrzywolski	Combined multiple policies into single version.
5/7/2014	D. Odrzywolski	Grammatical updates
5/27/2014	C. Randle	Added language to address confirmed criminal convictions.
9/23/2014	M. Norman	Included additional regulatory references relating to FEHBP
9/1/2015	C. Kosinski	Revised – Minor Changes
10/26/2016	D. Odrzywolski	Revised – Minor changes and removed OMIG Terminations and added Medicare Opt-out Auto Renewal
1/1/2017	D. Odrzywolski	Revised – Minor Changes
1/1/2018	D. Odrzywolski	Revised – Minor changes including added references.
1/1/2019	N. Britton	Revised – Minor Changes

1/1/2020	N. Britton	Revised to update processes
1/1/2021	N. Britton	Revised and consolidated with Medicare Opt Out Provider Policy (A20160106001) and Medicare Preclusion List Policy (A20191016053)
1/1/2022	N. Britton	Reviewed, minor changes
1/1/2023	N. Britton	Reviewed, no changes
1/1/2024	N. Britton	Revised – Process updates and Regulatory References
1/1/2025	N. Britton	Reviewed, minor changes
3/1/2025	N. Britton	Revised – Clarified ineligibility disclosure requirement and updated policy sponsor