SUBJECT: Quality of Care Risk **Investigations Policy BUSINESS OWNER:** Quality Improvement **Page** _ 1 **of** 10 Approved by: **APPROVED BY:** Accreditation Team Accreditation Team 11/1/2021 **EFFECTIVE:** 07/19/04 **REVISED:** 11/16, 4/2018, 12/2019, 11/2021 Joshua Plavin, MD, MPH, MBA Date **NEXT REVIEW** Vice President and DATE: Chief Medical Officer 11/2023

APPLIES TO: All Lines of Business

REGULATORY / ACCREDITATION LINKS:

2022 NCQA HPA Standards and Guidelines: ME 1, ME 7A, ME 7C-F, CR 5, NET 1-3

Vermont Rule H-2009-03: 1.5A, 6.3B8 American with Disabilities Act (ADA)

RELATED POLICIES:

Complaints Policy

Credentialing Policy

Facility Credentialing Policy

Accessibility and Provider Administration Service Standards Policy

Provider Contract Termination Policy

Clinical Practice Guidelines Policy

Records Retention and Management Policy

Never Events and Hospital Acquired Conditions Corporate Payment Policy

IH 34- Medical Policy Development and Review Policy

I. **Policy**

Blue Cross and Blue Shield of Vermont (Blue Cross) identifies and, when appropriate, acts on important quality and safety events in a timely manner at any time following the formal credentialing process. Blue Cross collects member complaints as well as issues/concerns from internal departments and network providers according to the risk categories identified in this

policy, and initiates a risk investigation within 30 days. Blue Cross evaluates both the specific quality of care matter reported and the practitioner's history of quality of care events. In keeping with Blue Cross's mission to "always put the member experience first," all complaints and issues/concerns are reviewed for poor health care quality resulting in harm to a member or creating high potential for causing harm to a member. The Blue Cross credentialing committee peer reviews cases and may take action on quality of care complaints and issues/concerns.

II. Definitions

- **a. Quality of Care**: The degree to which health care services for individuals and populations increase the likelihood of desired health outcomes, decrease the probability of undesired health outcomes and are consistent with current professional knowledge.
- **b. Complaint**: Any communication, written or verbal, which is an expression of dissatisfaction with any aspect of the Plan or the resolution of a previous inquiry. These include situations caused by an error or an inconvenience or oversight made by Blue Cross, a provider both in and out of state, or a third-party vendor.
- **c. Issue/Concern**: A quality of care or service issue arising from an internal review of care or an anonymous report.
- **d. Adverse Event**: An injury that occurs while a member is receiving health care services from a practitioner.
- **e. Peer Review**: Evaluation or review of colleague performance by professionals with similar types and degrees of expertise.
- **f. Clinical Investigator**: A licensed clinician who investigates and processes quality of care cases.
- **g. Risk Investigation:** The review process the clinical investigator uses to review and process quality of care cases.

III. Scope

This policy affects all network practitioners, facilities, durable medical equipment providers, community agencies and clinics that contract with Blue Cross. Blue Cross requires all providers to participate fully with quality of care investigations. This includes providing all documentation, policies, and procedures as requested. Participation in performance improvement activities resulting from quality of care investigations is a contractual obligation for the Blue Cross's provider network. Blue Cross collects and reviews all complaints and issues/concerns received about providers and all adverse events identified. Blue Cross identifies instances of poor quality and implements appropriate interventions.

IV. Receiving Quality of Care Cases

- **a.** Members: Any Blue Cross employee from any department can receive a formal member complaint or member request for an investigation into a quality of care matter by any means of communication including but not limited to phone, email, or secure message. If the member wishes to file a formal complaint, the member will be referred to Customer Service and the "Complaints Policy" will be followed. A quality of care case will be submitted, if necessary, in accordance with that policy.
- **b.** Providers: Any network practitioner or agent of a network provider may report a quality of care issue/concern to any Blue Cross employee.

- **c.** Blue Cross Staff: Any Blue Cross employee member may report a quality of care issue/concern identified during the course of regular work or interactions with members and practitioners.
- **d.** All reports of quality of care complaints or issues/concerns are entered into the system by either the Blue Cross employee who receives the complaint or issue/concern or by the clinical quality staff member who receives the report.
- **e.** Never Events and Hospital Acquired Conditions: Quarterly reports are received from the Inter-Plan Programs Department, as well as the Reimbursement and Analytics Department, containing claims that have a diagnosis code which may indicate a never event or hospital acquired condition. These cases are reviewed; if a risk investigation is warranted, they are entered into the system and the risk investigation is performed as appropriate.

V. Intake Procedure Prior to Initiating Risk Investigation

Quality improvement staff review all quality of care cases. The clinical investigator needs certain information before deciding how and whether to proceed with a risk investigation. Intake information should contain as much of the following information as possible:

- Summary of complaint or issue/concern
- Name of provider
- Date(s) of service
- Description of harm to member
- Claims review
 - Procedures completed
 - Co-morbidities
 - Medical care history
- Interview with reporter of event

To protect the welfare and safety of our members, all quality of care cases received will be reviewed by the Quality Improvement staff, and any potential safety concerns are to be reported to a Blue Cross Medical Director within two business days of receipt. This includes, but is not limited to, reports of potential never events or hospital acquired conditions (see Never Events and Hospital Acquired Conditions Corporate Payment Policy), medication adverse events, unusual infections, and unsafe transitions in care.

VI. Quality of Care Categories

Following the intake process, and within 30 days of receipt of the case, the clinical investigator categorizes the complaint or issue/concern by assigning a risk category to describe the quality of care event. Within the primary risk categories there are sub-categories to describe the specific type of complaint or issue/concern. Some complaints or issues/concerns may fit under multiple risk categories and this should be documented in the system.

Risk Categories and Sub-Categories

Quality of Care

- Care unacceptable
- Treatment outcome unacceptable

Never events

Access

- Difficulty obtaining appointment
- Office hours
- Difficulty after hours
- Telephone access

Attitude and Service

- Provider behavior unacceptable
- Provider communication unacceptable
- Office staff rude
- Office wait time

Billing or Financial Issues

Billing or coding concerns

Quality of Practitioner Office Site

- Office appearance unacceptable
- Adequacy of medical record or treatment record keeping
- The clinical investigator investigates all cases that result in reported physical harm to the member.
- In each case, the clinical investigator considers the level of harm the member incurred, the potential for future harm to this member or other members, and the continuing needs of the members affected before starting the investigation.
- If the clinical investigator discovers potential or existing medical or service needs, the clinical investigator refers the member to the appropriate Blue Cross department for assistance, while continuing the quality of care risk investigation.
- These needs include, but are not limited to, the following:

Member Needs	Referral Department
Benefits, billing, claims	Customer service
Navigating the healthcare system	Member ombudsman
Acute medical and/or mental health needs	Case Management
Fraud and waste concerns	Payment Integrity

VII. Risk Investigation

The clinical investigator considers the following elements in reviewing the case and assessing whether a quality of care matter is present:

- Provider or practitioner technique, knowledge, judgment, action, failure to act, communication, etc.
- Patient action, failure to act or communicate, compliance with care plans or instructions, etc.
- Systems within the specific care setting
- External factors; i.e., factors over which the practitioner, patient, and/or care setting had no control
- Mitigating factors

The clinical investigator may include any or all of the following in the investigation:

- a. Interviewing Complainant or Reporter: Blue Cross clinical investigator may call the member or case reporter to clarify events, obtain more details, check for on-going case management needs of members, and help manage member expectations for complaint resolution.
- b. Reviewing the Recorded Complaint or Issue/Concern: Blue Cross records the calls received by customer service. If a case originated with customer service, the investigator may retrieve the call to gain further understanding of the nature of the complaint or issue/concern and clarification of the reported events.
- c. **Claims Review**: The clinical investigator may conduct a claims review to ensure the care occurred. Claims review also provides other relevant information such as co-morbidities and other providers involved.
- d. Authorization History: The clinical investigator may conduct a review of the member's authorization history. This may include authorizations reviewed internally by Blue Cross's Utilization Management department and documented in its care management system or externally through the pharmacy benefit manager and any other utilization management delegates.
- e. **Requesting Medical Records**: If the risk investigation requires review of the medical care received by the member, the clinical investigator may request related medical records from the involved providers. This information may extend beyond the time of the reported event and may include records describing member's condition prior to and after the reported event. The clinical investigator faxes a request to the relevant providers. Blue Cross expects providers to return the requested information within 14 days.
- f. **Site Visit and Medical/Treatment Record Review:** The clinical investigator may conduct an unannounced site visit if the Blue Cross is in receipt of a member complaint concerning any of the following within 60 days: physical accessibility, physical appearance, waiting/exam room space adequacy, adequacy of medical/treatment record keeping.
- g. Other Department Activity: The clinical investigator reaches out to other Blue Cross departments as appropriate to see if other activity pertaining to the complaint or issue/concern has occurred. This may include but is not limited to: provider relations, payment integrity, customer service, utilization management, case management, network management, and the legal department. Representatives from these other departments may be included in investigative activities.
- h. Provider/Facility Outreach: The clinical investigator may contact providers involved to clarify events, procedures, policies and actions already taken by the provider or staff to resolve the matter. Provider relations staff may assist in communicating with providers. This outreach may also include communication with facility quality departments, risk management departments or office managers for large facilities.
- i. **Literature Review**: The clinical investigator may compare the documented care provided against Blue Cross published guidelines, consistent with the Blue Cross "Clinical Practice

Guidelines Policy." If the care provided is not addressed in that policy, the clinical investigator may use other resources that are considered to provide medical or scientific evidence, including but not limited to: UptoDate, MCG, CDC, NIH, evidence-based guidelines and positions of leading national health professional organizations, and specialty society guidelines. Other acceptable resources can be found in "IH 34 Medical Policy Development and Review Policy." After reviewing the literature, the clinical investigator would compare the appropriate guidelines to the care received.

- j. **Credentialing and Performance Review**: The clinical investigator may use both past and present credentialing and provider performance data to substantiate quality of care matters when presenting to the credentialing committee for their recommendations.
- k. Medical Director Review: When the clinical investigator determines a quality of care matter exists, at a level three and above (based on the Impact Score discussed below), he or she presents the case to Blue Cross's Chief Medical Officer (CMO) or a medical director. The CMO or the CMO physician designee completes a peer review of the case. Should the Blue Cross's physician reviewer not have the expertise to complete a fair peer review, he or she may refer the case to a consulting physician with the appropriate training and experience. The Blue Cross physician assists in determining risk stratification by determining the level of harm incurred by the member, the degree of provider consistency with current clinical guidelines, and any possible mitigating circumstances affecting the care provided.

VIII. Risk Investigation Outcomes

If the clinical investigator decides that a quality of care matter exists, Blue Cross determines the severity of a quality of care case with a metrics system. The Blue Cross clinical investigator or medical director (if physician review was required) consider the actual or potential impact of the quality of care issue and the probability of the issue's reoccurrence based on the scope of the identified issue. The risk determination for each case is decided using the following tables.

Impact Level

Level	Impact Score
Not Leveled	Quality of care concern withdrawn by member or followed by a Blue Cross and Blue Shield Association host plan.

Five	Resulted in a significant adverse clinical effect on the member (permanent or death).					
Three	Had the potential to cause a significant adverse clinical effect (i.e., potential for level five) on the member, but it did not result in this situation. Or caused a major but temporary clinical effect with no long-term impact to the member (e.g., burns, drug side-effect).					
Two	Had the potential to or caused a temporary insignificant or minor adverse clinical effect on the member (e.g., lacerations, contusions, minor scars, rash, infections, missed fractures, fall in hospital, no delay in recovery, recovery delayed without long-term impact to the member).					
One	Adverse effect caused to member in the form of fright, emotional harm, or financial harm.					
Zero	Unlikely to cause an adverse clinical effect on the member (e.g., miscommunication and/or interpersonal conflicts between member and practitioner and/or office staff).					

Probability of Reoccurrence

Probability Level	Scope of Issue					
Very High	Facility System Design or Philosophy					
High	Practice System Design or Philosophy					
Medium	Shared Across a Particular Provider Type					
Low	Single circumstance, not attributable to system or philosophy; either human error or an unlikely but known risk of care					
Very Low	Blue Cross clinical team determines error unavoidable due to mitigating circumstances					

Risk Determination Chart

	Impact Level						
of		0	1	2	3	5	
Probability (Very High	5	10	20	40	80	
obak	High	4	8	16	32	64	
P 8	Medium	3	6	12	24	48	

Low	2	4	8	16	32
Very Low	1	2	4	8	16

Outcome of Investigation:

- **Red (21-80)** Credentialing committee reviews and takes disciplinary or corrective action
- **Yellow (11-20) -** Credentialing committee reviews and may take disciplinary or corrective action
- **Blue (5-10)** Quality staff monitors for trends and alerts provider and/or facility to situation
- **Green (1-4)** Quality staff monitors for trends; no further action required

If no quality of care matter exists, the case is closed, the member's medical records will be destroyed per company policy, and all relevant information supporting that decision is documented in the system.

IX. Credentialing Committee

The clinical investigator presents to the CMO, CMO designee, or a medical director and the credentialing committee, any provider who is the subject of any quality of care complaint or issue/concern that ranks in the yellow or red categories, or is the subject of three cases within 18 months ranking in the green or blue categories.

Blue Cross's credentialing committee reviews the case and determines next steps. The committee oversees any resulting corrective actions for providers in accordance with the Blue Cross "Credentialing Policy and Provider Contract Termination Policy." Actions may include, but are not limited to: requests for a corrective action plan, a comprehensive chart review, limited credentialing periods, suspension, or termination from the network. Providers may appeal the credentialing committee decisions as outlined in the above referenced policies.

If a trend is noticed in cases received regarding a provider who is not credentialed through our credentialing process (including, but not limited to, durable medical equipment providers), quality matters can be discussed with provider relations and contracting for appropriate actions.

X. Medical Board and the National Practitioner Data Bank Reporting

Blue Cross reports to the state medical board and NPDB in accordance with applicable laws and regulations. The clinical reviewer may consult the legal department about appropriate actions regarding any quality case.

XI. Fraud, Waste, and Abuse

Any suspected fraud, waste, or abuse is reported to the payment integrity department for potential recoupment of payment. This includes, but is not limited to, never events and hospital acquired conditions.

XII. Member Experience Team

Trends observed in quality of care cases will be presented semi-annually to the Member Experience Team, to help inform quality improvement projects.

XIII. Case Conclusion

- a. **Closing case:** The case will be closed within 120 days. If the circumstances of the investigation or follow-up actions require it to remain open beyond this amount of time, the documentation in the case will reflect the reason it remains open.
- b. **Member Communications:** Blue Cross may send the complainant a written communication at the conclusion of the risk investigation. This letter may include actions and future activities concerning the complaint or issue/concern. Consistent with peer review protection principles, Blue Cross will not include any findings related to provider practice. Blue Cross may also call the member to finalize the review without sharing specifics.
- c. **Member/Provider Education:** During the investigation, Blue Cross may identify a provider or member knowledge deficit that contributed to the quality of care case. Blue Cross may choose to provide education and information as deemed appropriate.
- d. **Provider Notification:** Blue Cross may alert the involved providers of the investigation and conclusion when appropriate.

XIV. Documentation of Process

- a. Blue Cross stores all communications, medical records and disciplinary actions related to a quality of care risk investigation in the Blue Cross's electronic files. Member's medical records will be stored electronically if there are quality of care matters confirmed. These files and records are accessible only by members of the quality improvement department, as well as the chief medical officer. Any additional access to these files must be approved by the director of quality.
- b. If no quality of care matters are confirmed, the member's medical records will be destroyed per company policy.
- c. Blue Cross maintains the information gathered in this peer review process as confidential and privileged.

XV. Policy Distribution to Providers

Blue Cross distributes this policy to network practitioners and appropriate staff members via the provider manual that is available on the Provider Resource Center.

XVI. Biennial Review

The accreditation team reviews this policy and procedure biennially and as needed to ensure consistency with current business practice and to incorporate the latest regulatory and accreditation standards.