SOUTH CAROLINA DEPARTMENT OF INSURANCE
INDEPENDENT REVIEW ORGANIZATION (IRO) APPLICATION

All independent review organizations seeking to conduct independent reviews in South Carolina must first be approved by the South Carolina Department of Insurance. This document summarizes the procedures for approving Independent Review Organizations (IRO) under S.C. Code Ann. §§ 38-71-2000 and 38-71-2240(F)(1)(b). Applicants should carefully review all requirements for performing reviews and the licensing of independent review organizations as delineated in S.C. Code Ann. §§ 38-71-1910 *et seq*.

PLEASE NOTE

No entity is qualified to submit an application if it owns or controls, is a subsidiary of or in any way owned or controlled by, or exercises common control with, any of the following: a health benefit plan; pharmacy benefit manager, a national, state or local trade association of health care providers or pharmacy benefit managers; or a national, state or local trade association of health benefit plans or pharmacy benefit managers. *See* S.C. Code Ann. § 38-71-2010 and S.C. Code Ann. Regs. 69-77 § VIII.H.

The initial application fee is $1,000 and the fee for reapproval is $500. It is effective from the date of approval and will continue in effect through September 30 of odd numbered years.

THE APPLICATION PACKET

The following documents must be completed and returned with the application for approval:

1. Application for Approval as an Independent Review Organization (Application for Approval)
2. Attachment A - Biographical Affidavits for all directors, officers, executives, owners, and the medical director (or clinical director).
3. Attachment B – No Conflicts of Interest Certification
4. Attachment C - Certification of Impartiality of Reviewer

In addition to the items included in this packet, the application should include a letter of transmittal with an index using the identification system described in these instructions. An explanation for the omission of any material should accompany the application. Please include the application fee made payable to the South Carolina Department of Insurance based on the appropriate application type. Mail one original application packet with all attachments (application packet) and email one copy of the application packet to:

Attn: Market Regulation
IRO APPLICATION
South Carolina Department of Insurance
P. O. Box 100105
Columbia, SC 29202-3105
Email Address: MarketReg@doi.sc.gov

IRO APPLICATION

Please complete the application form in its entirety. Do not leave blanks. If a question is not applicable to your organization, please include Not Applicable or NA in the blank. Please explain why the question is not applicable to your organization in your transmittal letter.

Please arrange the materials accompanying your application in the following order:

I. Organizational Structure, Management and Service Providers

A. Copy of the Certificate of Authority from the South Carolina Secretary of State.

B. Copy of the articles of incorporation, articles of organization and bylaws or operating agreement for the IRO, holding company or parent company.
C. Organizational chart that depicts the Applicant's management and administrative staff.
D. Names of all corporations and organizations owned or controlled by the IRO, or which owns or controls the IRO, and nature and extent of such ownership or control.
E. List and describe the scope and relationship of all agreements between the IRO and insurance companies, claims administrators, health care services entities, health care providers and management service organizations.
F. A chart showing the Applicant's contractual arrangements with all persons authorized to conduct business with, for, or on behalf of the Applicant related to its business as an IRO or the external review services it provides.
G. A description of and evidence of accreditations from nationally recognized organizations.
H. A list of personnel and their qualifications contracted to provide services for Applicant.

II. Independent Review Plan

A. Regulatory Compliance Plan
Please describe:

1. Procedures to track and to ensure compliance with applicable laws and regulations.
2. Procedure to maintain a current list of conflicts of interest.
3. If any review functions are delegated, procedures to ensure that subcontractor follows all applicable laws and regulations.

Attach a copy of your organization's policies and procedures related to compliance.

B. Quality Assurance Plan
Please include:

1. A description of procedures to identify and resolve potential and actual problems including conflicts of interest.
2. Procedures to protect the confidentiality of medical records, review materials, and data related to the external review process consistent with applicable state and federal law.
3. A description of the medical or clinical director's role.
4. A description of the IRO's Quality Assurance Mechanism that ensures external reviews are completed within specified timeframes and notices are provided timely.
5. A description of procedures to ensure that management reports are adequate to track and monitor all aspects of the quality assurance program.

Attach a copy of your organization's policies and procedures related to quality assurance.

C. Peer Reviewers
Please include:

1. A description of any credentialing software used to manage the credentialing process.
2. A description of procedures to ensure the IRO has a sufficient number and types of peer reviewers for the types of reviews it intends to conduct.
3. A description of procedures to ensure the peer reviewers are appropriately licensed, registered, or certified, are trained in IRO standards, and are knowledgeable about the health care/pharmacy service

that is subject of the review. All non-clinical reviewers must have appropriate qualifications in routine business practices, such as auditing, accounting, provider reimbursements, or pharmacy reimbursements. All clinical peer reviewers conducting external reviews involving clinical judgment must be appropriate health care providers and include a pharmacist for PBM or pharmacy-related claims.

4. A description of procedures to ensure the suitable matching of peer reviewers to specific cases and to ensure that peer reviewer assigned to a review does not have a conflict of interest. Prior to assignment, the CEO completes Attachment C, attaches a copy of a signed statement from the peer reviewer that he/she has no conflict of interest, and submits it with the external review determination.
5. A description of methods for recruiting and selecting peer reviewers and for verifying qualifications at least every two years.
6. A description of procedures to conduct appropriate training, monitor performance on an ongoing basis and evaluate no less than annually each of the reviewers and nonclinical staff.

Attach a copy of your organization's policies and procedures related to your organization's peer review process.

D. Procedures for Handling Independent Review Requests
Please include:

1. A description of all aspects of the independent review process and chart or diagram of the sequence of steps from receipt of the independent review request through notification of the IRO's decision.
2. Procedures to ensure peer reviewer considers all pertinent information described in S.C. Code Ann. §§ 38-71-1910 *et seq*., (Health Carrier External Review Act), S.C. Code Ann. §§ 38-71-2200 *et seq*. and S.C. Code Ann. Regs. 69-77.
3. Procedures for ensuring the decision is consistent with the terms of the policy or health benefit plan and applicable state and federal law.
4. Procedure to ensure reviews are conducted and required notices provided within statutory and regulatory timeframes for both standard and expedited reviews.
5. A toll-free telephone number and procedures for ensuring adequate means to service.
6. Procedures for maintaining records and annual reporting, as required by §§ 38-71-2030 and S.C. Code Ann. Regs. 69-77.

E. IRO Fees

Please submit a copy of your fee schedule to the Department. Provide documentation to demonstrate that the proposed fees are based on prevailing rates in the industry including the actual costs for conducting reviews.

Mail one original application packet with all attachments (application packet) and email one copy of the application packet to:

Attn: Market Regulation
IRO APPLICATION
South Carolina Department of Insurance
P. O. Box 100105
Columbia, SC 29202-3105
Email Address: MarketReg@doi.sc.gov

IRO APPLICATION FORM

I. TYPE OF APPLICATION (Please check one)

- ☐ Original Application Fee: $1000
- ☐ Renewal Application Fee: $500, IRO #_____
- ☐ Update/Change to the Original Application: No fee, IRO Certification #_____

II. NAME OF INDEPENDENT REVIEW ORGANIZATION

Name of IRO:	
Other Names in which IRO does business:	
Company Address:	
Telephone:	
Fax:	
Website:	
Federal Employer Identification Number:	
Official Email Address:	

III. TYPE OF ORGANIZATION

☐ Corporation	☐ Limited Liability Company	☐ Partnership
☐ Association	☐ Other	

IV. TYPE OF APPEALS (check the ones of interest)

☐ Health/Medical Appeals	☐ PBM Appeals	☐ Other (Please Specify)	☐ All of the above

V. PRIMARY CONTACT PERSON FOR THE APPLICATION:

Name:	
Title:	
Telephone:	
Fax:	

Address (if different from above):	
Official Email Address:	
Does the IRO currently hold any accreditations?	☐ Yes ☐ No
If yes, please list accreditations:	
Has any accreditation status ever been revoked or suspended?	☐ Yes ☐ No
If yes, please explain:	

VI. PRIMARY CONTACT FOR COMPLAINTS

Name of Primary Contact:	
Email:	
Mailing Address:	
City:	
State:	
Telephone Number:	

VII. ORGANIZATION AND MANAGEMENT OF INDEPENDENT REVIEW ORGANIZATION

A.	**CORPORATE MANAGEMENT**		
	1.	Please complete the following and submit Attachment A if changes have been made for each person so described or his/her equivalent:	
		Chief Executive Officer	
		Name:	
		Title:	
		Telephone:	
		Fax:	
		Email:	

		Address: (If different from address above)	
		Corporate Medical Director	
		Name:	
		Title:	
		Telephone:	
		Fax:	
		Email:	
		Address: (If different from address above)	
		Director of IRO Operations	
		Name:	
		Title:	
		Telephone:	
		Fax:	
		Email:	
		Address: (If different from address above	

VIII. FINANCIAL ARRANGEMENTS

Provide the following current financial data for the applicant:	
1.	Statement of Revenues and Expenses
2.	Current Balance Sheet
3.	Audited Financial Statement or Equivalent Acceptable to the Director for the past three years
NOTE:	If any of the information provided in this application is considered to be exempt from disclosure pursuant to South Carolina Code of Laws Section 30-4-40, conspicuously mark it as such.

IX. Certification of Compliance and Verification

I, _____ (Name of Affiant) duly sworn do hereby in my official capacity as _____ (Title) certify that I have read and understood the application and attachments and attest to the accuracy and completeness of this application, and certify that there have been no material changes in qualifications, including removal or loss of accreditation by a nationally recognized private accrediting entity and including disciplinary actions or sanctions, as previously approved by the director or his designee. Additionally, I do hereby certify under penalty of applicable law that Applicant does not own or control, is not a subsidiary of or in any way owned or controlled by, or exercise common control with a health plan; a PBM; a national, state or local trade association of health care providers; a national, state or local trade association of health benefit plans; a national, state or local trade association

of PBMs; or a national, state or local trade association of a pharmacy. I understand further that this is a condition of licensure and any violation of this prohibition or other provisions of South Carolina law will result in the forfeiture of approval as an Independent Review Organization in this state and other administrative penalties set forth in the South Carolina Insurance Law.

Signature of Chief Executive Officer:	
Printed/Typed Name:	
Date:	

Sworn to or affirmed and subscribed before me this_
_____day of_____, 20_____

Signature of Notary_____

Name of Notary_____

Notary Public for the State of _____

My Commission Expires:_____

Attachment A
BIOGRAPHICAL AFFIDAVIT

A. PERSONAL IDENTIFYING INFORMATION:

Name:	
Title:	
Business Address:	
Telephone:	
Date of Birth:	
Place of Birth	
Social Security Number:	

B. INDIVIDUAL EMPLOYMENT HISTORY, LICENSES AND EDUCATION

Attach a resume reflecting relevant experience, licenses, and education. Include the names and contact information of at least three professional references.

C. HISTORY OF LEGAL OR DISCIPLINARY ACTIONS OR SANCTIONS

1.	Except for minor traffic violations, have you ever been indicted, been convicted, pled no contest, had a sentence imposed, suspended, or been pardoned on a conviction for any crime? ☐ YES ☐ NO
2.	Are there any criminal actions pending against you? ☐ YES ☐ NO
3.	☐ Have you ever been named as a defendant in any civil action or proceeding in which allegations were made against you involving moral turpitude, including but not limited to fraud or breach of fiduciary responsibility? ☐ YES ☐ NO
Note:	If "YES" to 1, 2, or 3, attach explanation(s) including the date of the action or proceeding, place (county of the filing), the civil docket number and the disposition of the case.

BIOGRAPHICAL AFFIDAVIT

4.	Have you ever been an owner, officer, trustee, management employee or controlling stockholder of an entity which, while you occupied any such position or served in any such capacity with respect to it: a. suffered the suspension or revocation of its certificate of authority or license to do business in any state? ☐ YES ☐ NO b. was denied a certificate of authority, license, or contract to do business in any state? ☐ YES ☐ NO
5.	Has your medical license or any other professional license or certification ever been suspended, revoked, or otherwise sanctioned? ☐ YES ☐ NO ☐ Not Applicable
Note:	If "YES" to 4 or 5, attach an explanation.
6.	Please list any medical malpractice actions initiated against you in the last five years. ☐ YES ☐ NO ☐ Not Applicable
	I hereby attest to the accuracy and completeness of this biographical information and consent to any investigation by the SCDOI to verify the information, including a criminal background check.

Signature		Date	

Sworn to or affirmed and subscribed before
me this_____day of____, 20__

Signature of Notary _____

Name of Notary_____.

Notary Public for the State of: _____.

My Commission Expires: _____.

ATTACHMENT B
NO CONFLICT OF INTEREST CERTIFICATION

TO BE EXECUTED BY THE CEO ON BEHALF OF THE CORPORATE ENTITY, OWNERS, OFFICERS, DIRECTORS, MEDICAL DIRECTOR, AND MANAGEMENT EMPLOYEES OF THE APPLICANT.

I.	**Whereas,** the applicant for certification as an Independent Review Organization shall not own or control, be a subsidiary of or in any way be owned or controlled by, or exercise common control with any of the following: (a) a health benefit plan; (b) a PBM; (c) a national, state or local trade association of health care providers; (d) a national, state or local trade association of health benefit plans; (e) a national, state or local trade association of PBMs; or (f) a national, state or local trade association of a pharmacy.
II.	**Whereas,** no Independent Review Organization or officer, director, or management employee thereof, nor any non-clinical or clinical peer reviewer employed or engaged thereby to conduct any external appeal pursuant to this title, shall have any material professional, familial, or financial conflict of interest in relation to an external appeal, with any of the following: (a) a health carrier or PBM that is the subject of the external review; (b) the pharmacy or covered person whose treatment is the subject of the external review of his authorized representative; (c) any officer, director, or management employee of the health carrier or PBM that is subject of external review; (d) the health care provider or the health care provider's medical group or independent practice association recommending the health care service or treatment that is the subject of external review; (e) the facility at which the recommended health care service or treatment would be provided; or (f) the developer, wholesaler, or manufacturer of the principal drug, device, procedure, or other therapy whose treatment or prescription is the subject of external review.

Now therefore, I,_____, in my capacity as Chief Executive Officer of the applicant do certify, attest and affirm under penalty of perjury that _____ _____(Applicant) has no disqualifying relationship as described in Section I above, and further, that I will ensure that neither Applicant nor any of its owners, officers, directors, Medical Director, management employees, or non-clinical or clinical peer reviewers currently employed or engaged, or future employees, have any material conflict of interest with any person or entity set forth in South Carolina law except as indicated on the attached sheet(s) incorporated and made as part hereof.

Signature of CEO		Date	
Printed Name			

Sworn to or affirmed and subscribed before me this_
_____day of_____, 20_____

Signature of Notary_____

Name of Notary_____

Notary Public for the State of _____

My Commission Expires:_____

ATTACHMENT C
CERTIFICATION OF INDEPENDENCE AND QUALIFICATIONS OF THE REVIEWER

TO BE EXECUTED BY THE CEO ON BEHALF OF THE CORPORATE ENTITY, OWNERS, OFFICERS, DIRECTORS, MEDICAL DIRECTOR, AND MANAGEMENT EMPLOYEES OF THE APPLICANT.

Independent Review Information

IRO Case Number _____ **Requestor's Name**_____

I.	**Whereas,** the applicant for certification as an Independent Review Organization shall not own or control, be a subsidiary of or in any way be owned or controlled by, or exercise common control with any of the following: (a) a health benefit plan; (b) Pharmacy Benefit Manager; (c) a national, state, or local trade association of health care providers; (d) a national, state, or local trade association of health benefit plans; (e) a national, state, or local trade association of PBMs; or (f) a national, state, or local trade association of a pharmacy.
II.	**Whereas,** no Independent Review Organization or officer, director, or management employee thereof, or peer reviewer employed or engaged thereby to conduct any external appeal pursuant to this title, shall have any material professional, familial, or financial conflict of interest in relation to an external appeal, with any of the following: (a) the health carrier or PBM that is the subject of the external review; (b) the pharmacy or covered person whose treatment is the subject of the external review or his authorized representative; (c) any officer, director or management employee of the health carrier that is the subject of external review; (d) the health care provider or the health care provider's medical group or independent practice association recommending the health care service or treatment that is the subject of external review; (e) the facility at which the recommended health care service or treatment would be provided; or (f) the developer, wholesaler, or manufacturer of the principal drug, device, procedure, or other therapy being recommended for the covered person whose treatment or prescription is the subject of external review.

Now therefore, I,_____, in my capacity as Chief Executive Officer of the applicant do attest and affirm under penalty of perjury that _____ _____**(Applicant):**

- has no disqualifying relationship as described in South Carolina law.
- neither Applicant nor any of its owners, officers, directors, Medical Director, management employees, or non-clinical or **clinical** peer reviewers currently employed or engaged have any material conflict of interest with any person or entity described in South Carolina law except as indicated on the attached sheet(s) incorporated and made as part hereof.

- has an unrestricted license, certification or registration in South Carolina and the following states [Please attach a document that lists all states, license numbers and expiration dates].
- There are no sanctions or revocations of the IRO's license, my license or license, certification, or registration by any state licensing agency in the United States or the United States Department of Health and Human Services of any person associated with the review of this matter.
- There are no disqualifying associations, business, or personal relationship with any of the involved parties who have provided or will provide care or advice regarding this case.

Signature of CEO		Date	
Printed Name			

Sworn to or affirmed and subscribed before me this
_____day of_____, 20_____

Signature of Notary_____

Name of Notary_____

Notary Public for the State_____

My Commission Expires: _____