Although relatively infrequent, claims against ophthalmologists arising from the screening for or treatment of ROP can be costly. There have been several published accounts of multi-million dollar awards and settlements, and OMIC’s average payout for ROP-related claims is significantly higher than the average settlement for any other ophthalmic activity. A large ROP judgment or settlement against you could have devastating effects on you. To reduce your risk of ROP-related claims and improve our ability to defend you should one arise, the company has developed underwriting requirements for physicians who render ROP services to infants when they are less than 55 weeks post-menstrual age (gestational age plus postnatal age).

1. Describe your training and experience specific to ROP, including fellowship training (if any). Date completed

_________________________________________________________________________            _____________________
_________________________________________________________________________            _____________________

2. OMIC has identified and evaluated an online ROP course that provides clinical considerations critical to ROP management. The course was created by FocusROP at http://www.focusrop.com/. All OMIC insureds who provide ROP services must successfully complete the FocusROP course.
   Have you completed FocusROP? □ Yes Date completed ________________________  □ No
   If no, please contact Linda Nakamura, Risk Management Coordinator, at lnakamura@omic.com or (800) 562-6642, ext. 652, to begin the registration process. OMIC will pay the course fee on your behalf. Completion of this course qualifies insureds for a risk management discount.

3. Which ROP services do you render to infants when they are less than 55 weeks post-menstrual age? (Check all that apply.)
   □ live screening – primary screener  □ live screening – backup screener  □ live screening – on rotation
   □ remote screening*  □ treatment

*OMIC’s professional liability policy extends coverage to ophthalmologists who provide ROP services when they use binocular indirect ophthalmoscopy (BIO) to determine an infant’s ROP status. Ophthalmologists who provide care at hospitals with retinal cameras may use the cameras as part of their documentation of the ROP exam. Coverage also applies to insureds who provide second opinions by reviewing retinal photographs taken in conjunction with another ophthalmologist’s BIO exam. However, the policy specifically excludes coverage for “remote screening” (i.e., evaluation of an infant’s ROP status by reviewing retinal photographs taken in the absence of a BIO exam.)

Coverage for “remote screening” is available only by special endorsement and is subject to review and approval of a supplemental questionnaire and adherence to OMIC’s underwriting requirements applicable to remote ROP screening.

4. A. If you are the primary screener, who provides backup? _________________________________
   B. If you are the backup screener, who provides primary screening? _________________________________
   C. If you screen on rotation, who are the other screeners? _________________________________
   D. Do you supervise residents or fellows involved in ROP screening or treatment? □ Yes □ No

5. Indicate your approximate ROP volume below:

   A. Screenings – live
      Next 12 Months
   B. Screenings – remote
      Last Year
   C. Treatments
      Past 5 Years

   Volumes above reflect the number of □ infants □ exams/treatments
For each hospital for which you provide ROP services, please indicate in the chart below the following information:

A. The NICU level. The official definition of NICU designations may vary from state to state. The following descriptions are provided as examples only. Please list the highest level that applies.

| Level 1 | Nursery that provides basic care to low-risk infants. |
| Level 2 | Nursery that provides specialty care to mildly ill infants who are at moderate risk of serious complications but whose problems are expected to resolve quickly. Level 2B can provide mechanical ventilation for short durations or continuous positive airway pressure. Level 2A nurseries do not have the capability to provide assisted ventilation except on an interim basis. |
| Level 3 | Nursery that provides subspecialty intensive care to high-risk infants. Level 3A nurseries provide care for infants with birth weights > 1000 grams and gestational age > 28 weeks. Continuous life support can be provided but is limited to conventional ventilation. Level 3B nurseries can provide comprehensive care for extremely low birth weight infants (≤1000 g and ≤ 28 weeks gestation), advanced respiratory care, on-site access to pediatric medical specialists, and advanced imaging and have pediatric surgical specialists on-site or at a closely related institution. Level 3C facilities have the same capabilities as 3B and are located within institutions that can provide ECMO (extracorporeal membrane oxygenation) and surgical repair of serious congenital cardiac malformations. |

B. The approximate number of screenings and/or treatments you performed at this hospital within the past year.

C. Whether the hospital has a written protocol assigning responsibility for each task in the ROP process. OMIC has developed sample protocols for both hospital- and office-based screening. “Retinopathy of Prematurity: Materials for Creating a Hospital ROP Safety Net” and “Retinopathy of Prematurity: Materials for Creating an Office ROP Safety Net” are available at http://www.omic.com/rop-creating-a-safety-net/. Please contact OMIC’s Risk Management Hotline for assistance at (800) 562-6642, option 4.

D. Whether the hospital maintains an ROP tracking system.

E. Whether the hospital has a qualified ROP coordinator (ROPC). An ROPC is a person with clinical knowledge and understanding of ROP, such as a NICU nurse or neonatologist, who assumes the responsibility for tracking infants until they meet end-of-screening/treating criteria (per the Policy Statement) or have been transferred to the care of an ophthalmologist in the office or another hospital. The ROPC should be someone other than the screening ophthalmologist. A sample Hospital ROPC Job Description is included in Appendix C of “Retinopathy of Prematurity: Materials for Creating a Hospital ROP Safety Net.”

F. Whether you are notified by the neonatologist prior to discharge or transfer of infants who meet screening or treatment criteria so that you can make and document follow-up recommendations.

G. Whether the hospital has a treating ophthalmologist on staff (OS) or a formal standing transfer agreement (STA) with a hospital with an ophthalmologist who can treat the infant.

<table>
<thead>
<tr>
<th>Hospital</th>
<th>A. NICU level</th>
<th>B. Screened (#)</th>
<th>B. Treated (#)</th>
<th>C. Written Protocol (Y/N)</th>
<th>D. Tracking System (Y/N)</th>
<th>E. ROPC (Y/N)</th>
<th>F. Discharge/transfer notification (Y/N)</th>
<th>G. Treating MD on staff or by transfer (OS/STA)</th>
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(Continue on a separate page, if needed.)

H. Please explain your “no” responses for Question 6C-G: □ Not applicable (all responses are “yes”)

____________________________________________________________________________________________________
____________________________________________________________________________________________________
____________________________________________________________________________________________________
____________________________________________________________________________________________________
Do you have a written protocol for office-based ROP services?  
☐ Yes  ☐ No  ☐ Not applicable (do not provide office-based services)


Are office staff members who answer phones:

A. Aware that you evaluate and/or treat premature babies with ROP?  
☐ Yes  ☐ No

B. Aware of the consequences of a delay in screening or treatment?  
☐ Yes  ☐ No

C. Trained how to identify calls about patients who might need ROP screening or treatment so they can be scheduled appropriately (i.e., do they ask if the infant is premature)?  
☐ Yes  ☐ No

A sample Office ROP Contact Form is available in OMIC’s “Retinopathy of Prematurity: Materials for Creating an Office ROP Safety Net” (Form 1).

Concerns about intravitreal anti-VEGF (IVAV) injections, such as Avastin™ (bevacizumab) or Lucentis™ (ranibizumab), as primary or salvage therapy for retinopathy of prematurity have been addressed in the literature and at eye society meetings. In addition, many questions are currently being studied and debated, such as agent, dosage amount, volume, timing of injections, length of follow-up, and contraindications. OMIC addresses these concerns and provides risk management recommendations in “Anti-VEGF Intravitreal Injections for ROP: Risk Management Analysis and Recommendations,” available at http://www.omic.com/rop-intravitreal-anti-vegf-injections-ris-management-recommendations/.

Infants treated for ROP with IVAV must be:

• Monitored weekly after injection; and
• Followed until full vascularization in close proximity to the ora serrata for 360º.

Please initial to confirm your understanding and agreement to abide by these requirements.

Initial: __________________

Do you ever administer IVAV injections for the treatment of ROP?  
☐ Yes  ☐ No  ☐ Not applicable (do not treat)

If yes:

A. In approximately what percentage of treatments are IVAV injections administered?  
__________________

B. Under what circumstances do you administer IVAV? (check all that apply)

☐ Failed laser treatment  ☐ Under an IRB-approved protocol
☐ Aggressive-posterior ROP (Zone I or posterior Zone II)  ☐ Other (specify: ________________________)
☐ Patient cannot tolerate anesthesia  ☐ Visibility impaired by blood or structures


Do you use OMIC’s sample consent form?  
☐ Yes  ☐ No

If no, please submit your consent form for IVAV treatment of ROP.

To be eligible for coverage of ROP services, you must comply with the following underwriting requirements (items 10–19, below). Please initial each item to confirm your understanding and agreement to abide by these requirements. Failure to comply with OMIC’s underwriting requirements (other than deviations specifically approved by OMIC) or to notify OMIC promptly of changes in your ROP protocol may result in uninsured risk or termination of coverage.

You must use the International Classification of Retinopathy of Prematurity (ICROP) Revised to classify, diagram, and record the retinal findings. ICROP Revised is published in Appendix B of OMIC’s “Retinopathy of Prematurity: Materials for Creating a Hospital Safety Net” and “Retinopathy of Prematurity: Materials for Creating an Office ROP Safety Net,” both of which are available at http://www.omic.com/rop-creating-a-safety-net/.

Initial: ____________
The “Dear Caregiver” letter (Form 2 of OMIC’s “Retinopathy of Prematurity: Materials for Creating a Hospital Safety Net and Form 3 of OMIC’s “Retinopathy of Prematurity: Materials for Creating an Office ROP Safety Net”) or a similar form must be completed for each infant examined, and the caregiver should be asked to sign the form, prior to the infant’s discharge from the hospital and upon the initial outpatient examination. These forms can be found at http://www.omic.com/rop-creating-a-safety-net. The handout is intended as a supplement to, and not a replacement for, communication with the caregiver. It serves as an important educational tool to explain the ROP process and the importance of timely follow-up. OMIC believes that use of a handout and associated parent education will help reduce the possibility of missed appointments.

Initial: _______________

Unless care has been duly transferred to another ophthalmologist as outlined below, you must screen each infant until both eyes have met the conclusion-of-acute-phase-ROP screening criteria or until a treating ophthalmologist has verified that treatment and all follow-up examinations have been completed (based upon criteria established in “Screening Examination of Premature Infants for Retinopathy of Prematurity,” the Policy Statement issued by the American Academy of Pediatrics (AAP) Section on Ophthalmology, the American Association of Pediatric Ophthalmology and Strabismus (AAPOS), and the American Academy of Ophthalmology (AAO). Originally issued in 1997 and updated in 2001, 2005, and 2012, the Policy Statement is published in Pediatrics (Volume 131, Number 1, 2013, http://pediatrics.aappublications.org/content/131/1/189.full.html.)

☐ Not applicable (do not screen) Initial: _______________

The maximum time interval between exams for infants less than 42 weeks post-menstrual age must be no longer than 3 weeks (in accordance with the Policy Statement).

☐ Not applicable (do not screen) Initial: _______________

When referring or transferring care of any infant 50 weeks postmenstrual age or younger to another ophthalmologist (such as from inpatient screener to outpatient screener or from screener to treater), you must conduct and document a transfer-of-care discussion with the next ophthalmologist, conveying the urgency of the referral, and ensure that he/she has copies of the patient’s previous examinations and has agreed to provide the care in the necessary time frame.

☐ Not applicable (do not refer or transfer care) Initial: _______________

You must personally maintain a system that tracks each infant from the time of the first visit (whether in the hospital or in the office) until the child has met the end-of-acute screening criteria of the Policy Statement or you have formally transferred care to another ophthalmologist. Studies have shown that redundancy creates safety. To create a “safety net” and minimize the risk of an infant being lost to follow-up, tracking must also be done by someone else in your office and in the hospital. Your tracking system must include the following elements:

A. Your practice must have an assigned office staff coordinator who is responsible for tracking ROP appointments in the hospital, scheduling ROP appointments in the office, and tracking no-shows. This ROP coordinator must be familiar with the Policy Statement and use it to review the appropriateness of follow-up intervals. OMIC has developed a sample Office ROPC Job Description, available in Appendix C of “Retinopathy of Prematurity: Materials for Creating an Office ROP Safety Net.”

B. Your tracking system must be updated each time the baby is evaluated or treated.

C. Your tracking system must be evaluated on a routine basis (at least once a week while infants are actively being screened or treated) to ensure that all follow-up appointments are scheduled and kept.

D. You must indicate the follow-up interval in the office chart. This should be expressed both in terms of time interval and date (e.g., two weeks, around May 2, 2010). The interval must be consistent with the Policy Statement: the longest period is 3 weeks, but many infants will need to be seen sooner than that.

E. The next office appointment must be scheduled before the caregivers leave the office.

F. Appointments must be reviewed on a daily basis, and you must be notified immediately of any changes in ROP appointments, including non-shows and cancelled or rescheduled appointments.

G. All follow-up efforts for missed, cancelled, or rescheduled appointments must be documented. (See Form 4 of “Retinopathy of Prematurity: Materials for Creating an Office ROP Safety Net” for a sample “missed appointment” letter.) Initial: _______________

The following requirements (16–19) apply to hospital-based ROP care.

☐ Not applicable (no hospital-based care rendered)
16. You and your office must **track ROP appointments** (see number 15 above). Initial: _______________

17. You must **include an ROP consult note** in the infant’s hospital chart at the time of each examination or treatment using the terminology of ICROP Revised. Initial: _______________

18. You must **indicate the follow-up interval** in the hospital chart. This should be expressed both in terms of time interval and date (e.g., two weeks, around May 2, 2010). The interval must be consistent with the Policy Statement: the longest period is 3 weeks, but many infants will need to be seen sooner than that. Initial: _______________

19. You must **personally notify the neonatologist and/or ROP Coordinator and document the recommendation** to begin treatment in the hospital record. If you do not provide treatment, you must conduct and document a transfer of care discussion with the treating ophthalmologist. If the hospital does not have a treating ophthalmologist on staff, you must write an order for an urgent consultation with a treating ophthalmologist so that the infant may receive treatment within 48 to 72 hours, consistent with the Policy Statement. To prevent a delay in treatment, the hospital must have a formal transfer agreement with an area hospital that does provide treatment. Initial: _______________

OMIC has developed the following ROP resource materials, available online at [http://www.omic.com/risk-management/ophthalmology/pediatric/](http://www.omic.com/risk-management/ophthalmology/pediatric/), to assist ophthalmologists. OMIC policyholders may also call the Risk Manager for confidential assistance at (800) 562-6642, extension 641 (option 4 from the main menu).

- “Retinopathy of Prematurity: Materials for Creating a Hospital Safety Net”
- “Retinopathy of Prematurity: Materials for Creating an Office ROP Safety Net”
- Office ROP Contact Form
- Sample ROPC Job Descriptions (NICU and office)
- “A ‘Watchful Eye’ on ROP” (Lead article, Winter 2010 Digest)
- Anti-VEGF Intravitreal Injections for ROP: Risk Management Analysis and Recommendations
- Sample consent form: “Intravitreal Anti-VEGF Injection for the Treatment of Retinopathy of Prematurity”
- “ROP Case Defines Legal Duty of Care to Patients” (Lead article, Summer 2005 Digest)
- “Shared Liability Limit for ROP Screening” (Policy Issues article, Fall 2003 Digest)
- “Staggering ROP Awards Scaring Doctors Away” (Lead article, Summer 2001 Digest)


Please initial the statement below that describes your compliance with the above underwriting requirements:

- __________ I have read and currently comply with OMIC’s underwriting requirements specific to retinopathy of prematurity (ROP).
- __________ I have read and currently comply with OMIC’s underwriting requirements specific to retinopathy of prematurity (ROP), with the exception of the following:

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<th>Explanation</th>
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I expect to be in full compliance by ____________________________.

Date

____________________________________________  ____________________________
Applicant’s Signature  Date

____________________________________________
Applicant’s Name (Please type or print.)