

CTRC OFFICE HOUR

Telehealth Diabetic Retinopathy Screening: A Modern Contracting Model

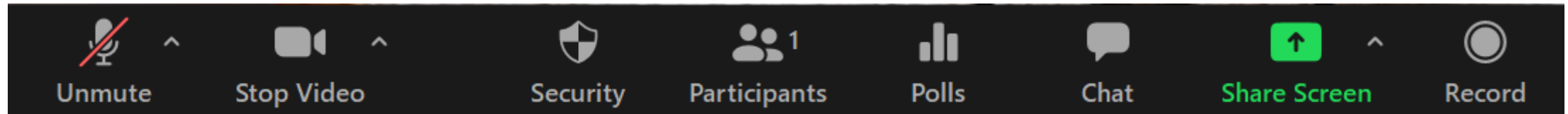
March 8, 2022

12 PM - 1 PM (PT)



Part of OCHIN

Zoom Tips



Muted on Entry

You are muted on entry. If you wish to comment or ask a question, you can unmute yourself.

Use Your Video

Please turn on the video for a more collaborative and engaging experience.

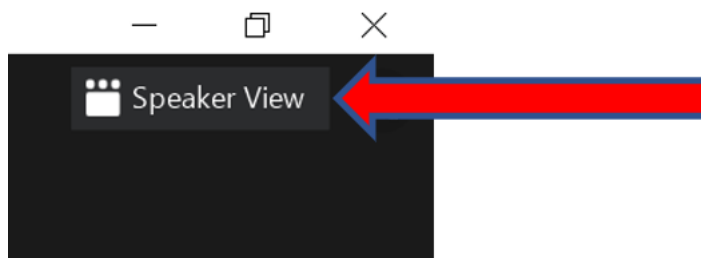
Open the Chat

Please open the chat and use it liberally; we want to hear from you!

Send questions and feedback to **"Everyone"**

Session Recording

We are recording today's session to capture LIVE responses for follow-up material. The recording will not be made public.



Speaker View vs Gallery View

At the top right of your screen you can change the video panel to just show the main speaker, or to gallery view to see the speaker and other participants, depending on your preference.

Before We Get Started

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We recommend discussing billing and legal decisions with your organization's compliance officer to ensure agreement or consulting with an attorney regarding any legal issue. All materials are strictly for informational and educational purposes only. CTRC has no relevant financial interest, arrangement, or affiliation with any organizations related to commercial products or services discussed in this session.

Meet The CTRC Team



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Executive Director



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Training and TA Manager



Aislynn Taylor
Program Specialist

Today's Hosts



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Chief of Telehealth &
Associate Clinical Professor



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Clinic Outreach Specialist &
Associate Clinical Professor

Digital Health Team

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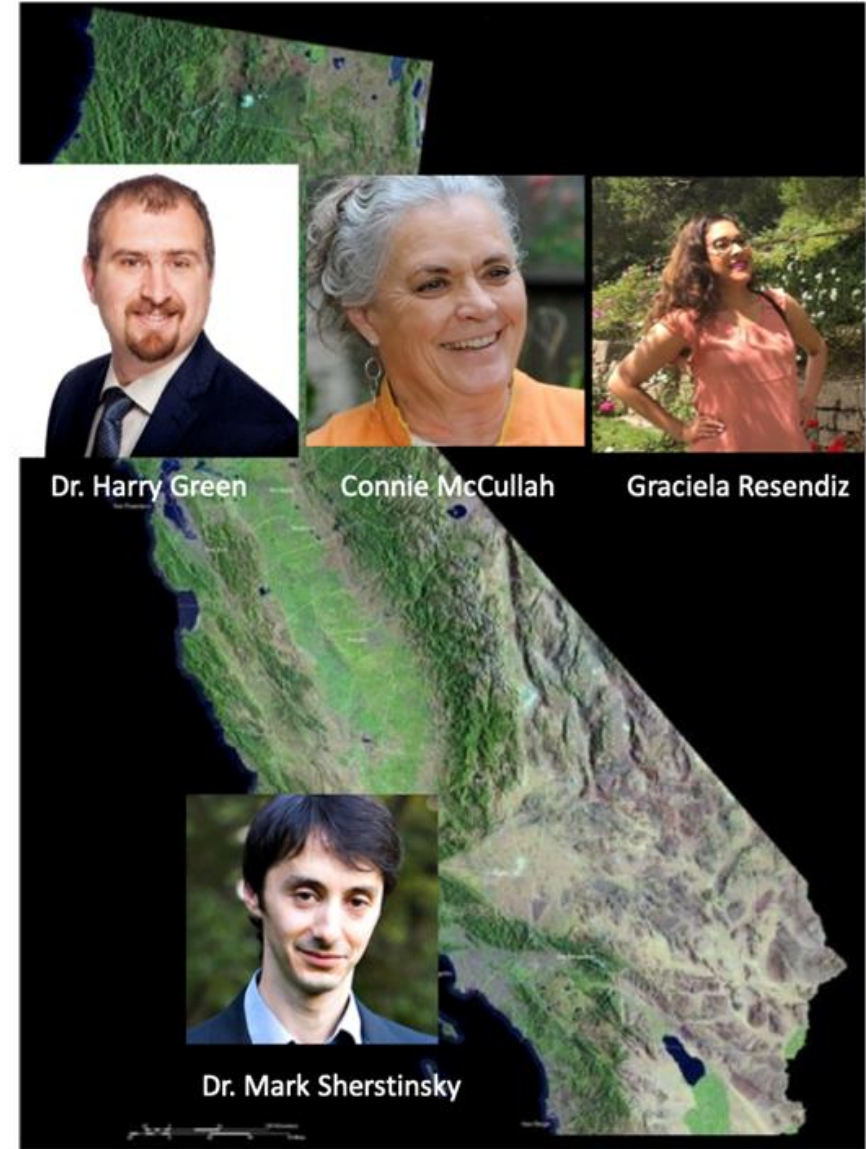
Today's Office Hours topics

- About Digital Health
 - EyePACS: our store-and-forward web portal site
 - Diabetic retinopathy screening guidelines and statistics
 - Implementing and maintaining a successful telehealth DRS program
- Billing and reimbursement (PPS)

About Digital Health

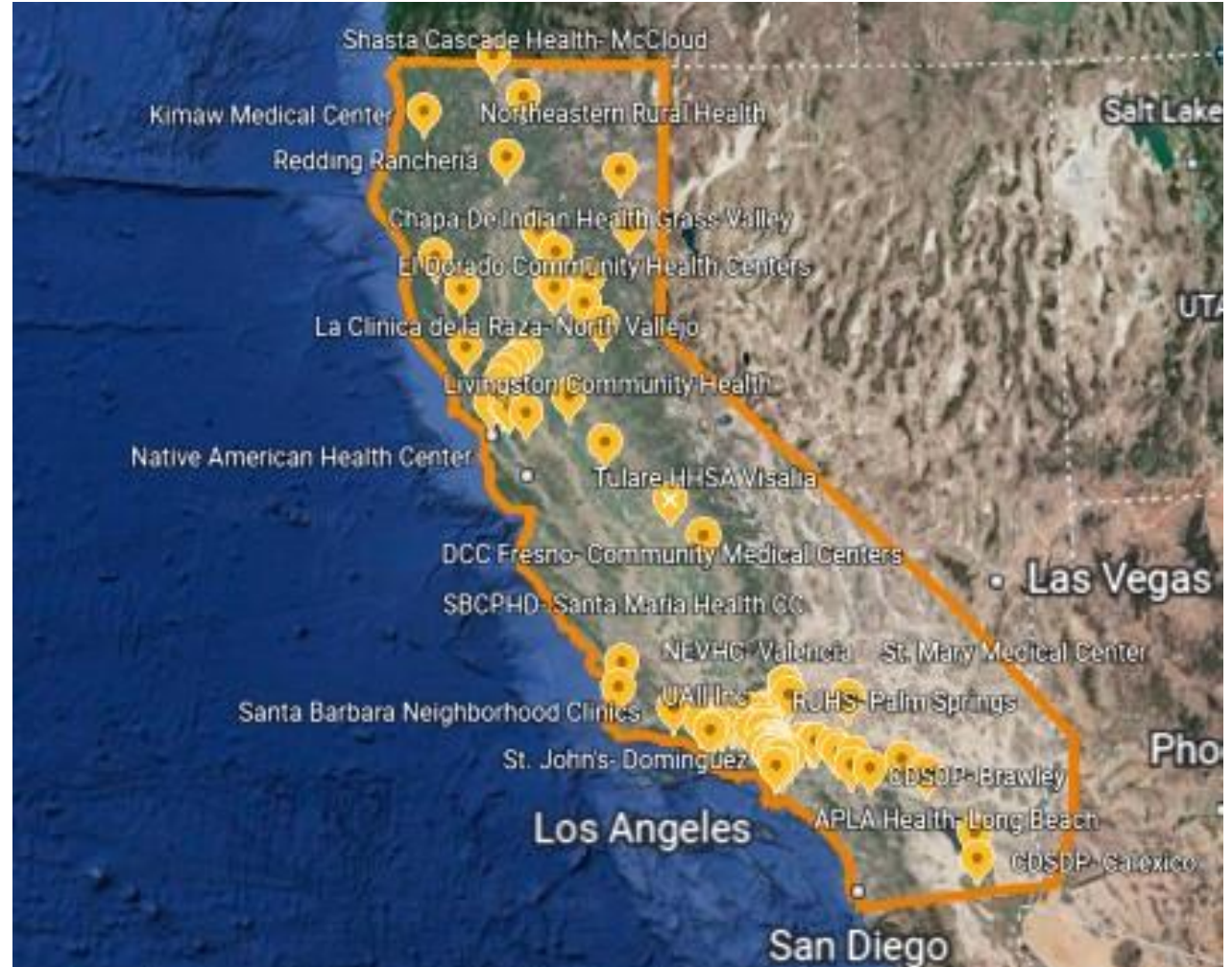
About Digital Health

- Professional point-of-care telehealth diabetic retinal diagnostic services, since 2005
- Mission: Prevent diabetic blindness in California
- Part of UC Berkeley Optometry
- Expanded with California HealthCare Foundation partnership in 2007



Where we work

- Digital Health works with over 100 health systems throughout California
 - FQHCs / RHCs / IHS
 - Hospitals
 - County Health Systems
 - Insurers
- Over 200 individual sites screening patients in California





EyePACS:
Secure, Web-Based Store-and-Forward Telehealth Platform
www.eyepacs.com

Our partner EyePACS: www.eyepacs.com



- Web-based platform, used internationally
- Allows communication between primary care staff & eye care clinicians
- *Store-and-forward* e-consults
- Secure & encrypted
- **A *validated* American Telemedicine Association Level 3-approved screening program (Levels 1 & 2 are less accurate / lower quality and may not qualify for HEDIS credit)**
- Interfaces with most EMRs



Dr. Jorge Cuadros, EyePACS CEO (2nd from left) in Guyana, South America

EyePACS seamlessly connects to EMRs & Information Systems

Interfaces are:

- Standards-compliant
- Bidirectional
- Secure
- Scalable

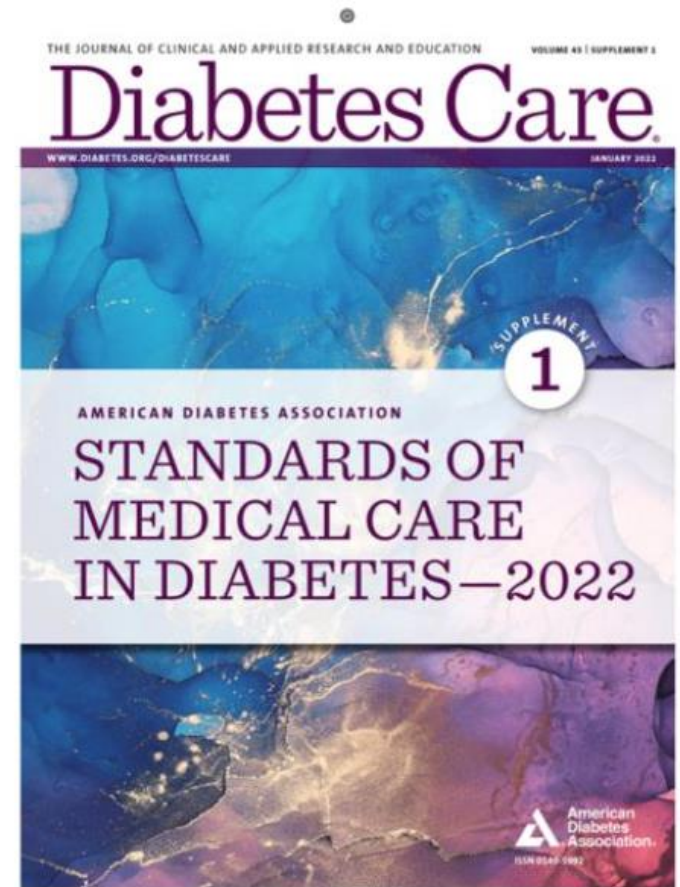


Diabetic retinopathy guidelines and statistics

ADA Standard of care for retinal screening: Annual eye exam

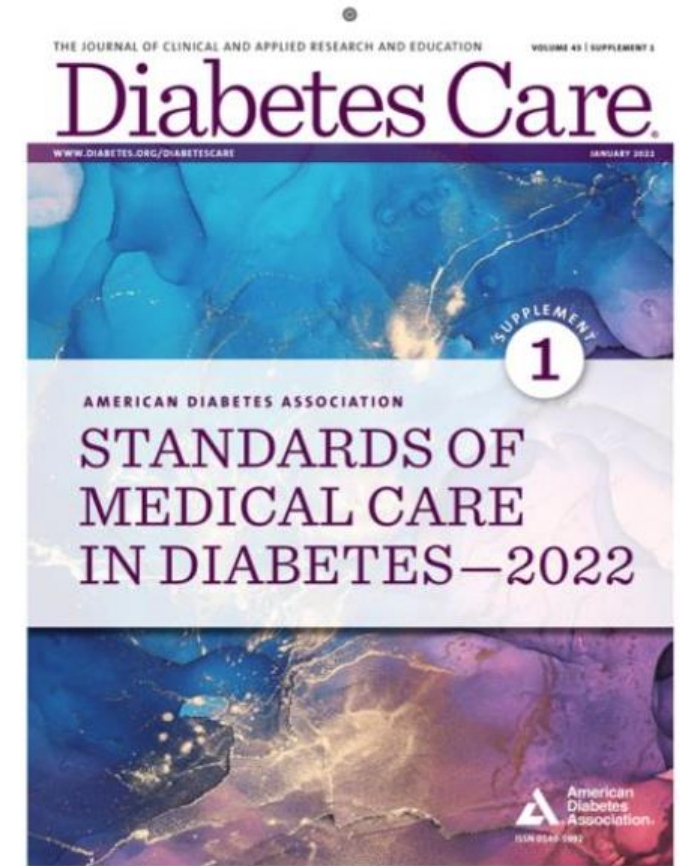
- Annual dilated exam or **high-quality imaging**
- More frequent exams if retinopathy is at a certain level or progressing
- Referral for treatment if sight-threatening retinopathy is present

https://diabetesjournals.org/care/article/45/Supplement_1/S185/138917/12-Retinopathy-Neuropathy-and-Foot-Care-Standards



ADA recommends retinal photography as a screening tool

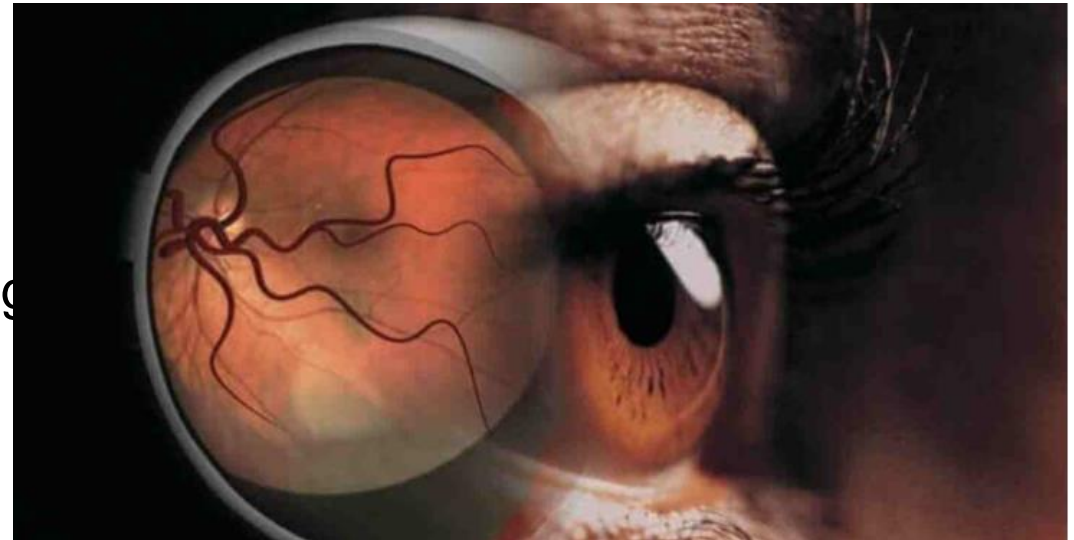
- “Programs that use **retinal photography** (with remote reading or use of a validated assessment tool) to improve access to diabetic retinopathy screening can be **appropriate screening strategies** for diabetic retinopathy.”
- “Retinal photography...has great potential to **provide screening services in areas where qualified eye care professionals are not readily available**”
- “...not a substitute for a comprehensive eye exam”



https://diabetesjournals.org/care/article/45/Supplement_1/S185/138917/12-Retinopathy-Neuropathy-and-Foot-Care-Standards (Recommendation 12.6)

Rising diabetic retinopathy prevalence: 1 in 12 patients with DM have risk of vision loss

- #1 cause of permanent blindness in US working-age adults
- WHO¹: after 15 years of DM
 - 2% will become blind
 - 10% develop severe visual handicap
- 8.2% of patients in safety-net/community clinics have sight-threatening diabetic retinopathy
= **1 in 12 patients**
- *With **timely** detection, treatment is **90%** effective in preventing severe vision loss²*



1 <http://www.who.int/ncd/dia/databases4.htm>

2 Landmark RCTs: DCCT, EDIC, DRS, ETDRS, DRVS

How are we doing in the US with DR screening?

Only half of all MediCal patients are compliant

COVID19 has affected rates significantly

2020 HEDIS US average retinal screening rates

- Medicare HMO: 68.3%¹
- Commercial HMO: 49.0%¹
- **Medicaid HMO: 50.6%¹**
- Rates are lower in underserved/safety net communities, especially rural communities
- COVID19 has reduced current rates to 2007 levels

'Eye Exams

| Measure Year | Commerical HMO | Commercial PPO | Medicaid HMO | Medicare HMO | Medicare PPO |
|--------------|----------------|----------------|--------------|--------------|--------------|
| 2020 | 49.0 | 46.9 | 50.6 | 68.3 | 68.5 |
| 2019 | 55.1 | 50.3 | 57.2 | § | § |
| 2018 | 55.9 | 49.6 | 57.4 | 74.2 | 72.7 |
| 2017 | 55.0 | 49.0 | 57.2 | 71.9 | 71.1 |
| 2016 | 53.6 | 47.5 | 54.9 | 70.4 | 69.6 |
| 2015 | 53.7 | 47.1 | 52.7 | 68.8 | 68.4 |
| 2014 | 56.2 | 48.7 | 54.4 | 68.5 | 68.4 |
| 2013 | 55.7 | 46.9 | 53.6 | 68.5 | 66.0 |
| 2012 | 56.8 | 48.8 | 53.2 | 66.8 | 64.6 |
| 2011 | 56.9 | 48.4 | 53.3 | 66.0 | 63.8 |
| 2010 | 57.7 | 45.5 | 53.1 | 64.6 | 62.3 |
| 2009 | 56.5 | 42.6 | 52.7 | 63.5 | 59.4 |
| 2008 | 56.5 | 35.8 | 52.8 | 60.8 | 52.2 |
| 2007 | 55.0 | 34.0 | 49.8 | 62.7 | 50.4 |

¹National Committee for Quality Assurance, Comprehensive Diabetes Care, Eye Exams
www.ncqa.org/hedis/measures/comprehensive-diabetes-care/

Telehealth is a solution to low DRS compliance

Point-of-care DRS can increase

- Laser therapy rate^{1,2} (increased blindness prevention)
- DRS compliance rate¹⁻³ (higher HEDIS measures)
- Provider referral rate¹⁻³ (higher provider incentives)



^{1,2}Wilson, C et al. (2005). Addition of primary care–based retinal imaging technology to an existing eye care professional referral program increased the rate of surveillance and treatment of diabetic retinopathy. *Diabetes* February 2005 vol. 28 no. 2 318-322

^{1,2,3}Taylor CR et al. Improving diabetic retinopathy screening care ratios using telemedicine-based digital retinal imaging technology: the Vine Hill study. *Diabetes Care*. 2007 Mar;30(3):574-8.

^{1,2,3}Olayiwola JN, Sobieraj DM, Kulowski K, et al. Improving diabetic retinopathy screening through a statewide telemedicine program at a large federally qualified health center. *J Health Care Poor Underserved*. 2011;22(3):804-16

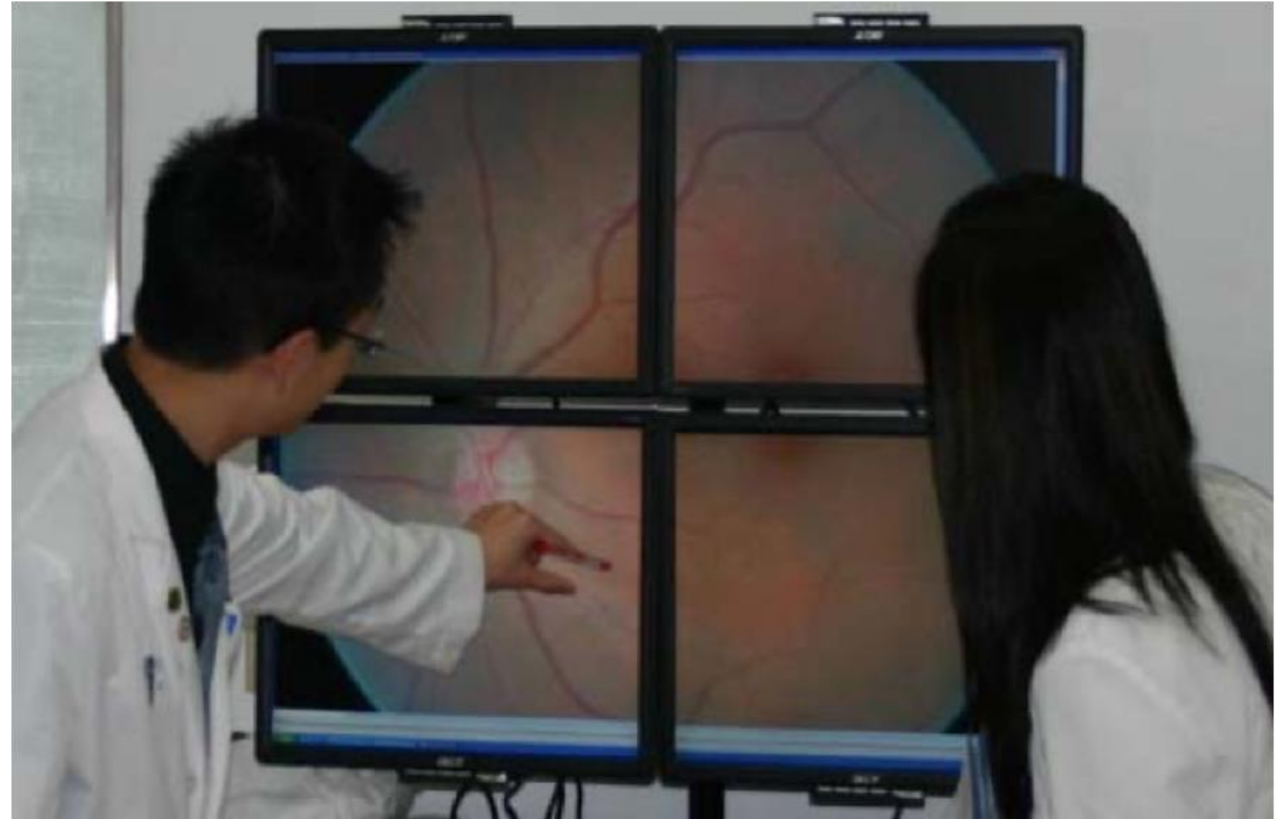
The evidence for effectiveness of retinal photography¹: Images are more effective than live viewing in detecting diabetic retinal lesions

16 clinical trials studied:

Live Ophthalmoscopy vs. Digital Imaging

Question: which was more effective at detecting retinopathy?

Results: **All studies showed viewing images are significantly more accurate than live retinal exam for detecting and grading diabetic retinopathy**



¹Whited JD. Accuracy and reliability of teleophthalmology for diagnosing diabetic retinopathy and macular edema: a review of the literature. Diabetes Technol Ther. 2006 Feb;8(1):102-11.

Success stories, pre-and-post Digital Health DRS: 2 FQHCs with increased DRS rates

Site #1 (began program June 2013)

–Pre-DH: 43.5% (May 2013)

–**Post-DH: 79.3%** (May 2014)

Site #2 (began program Feb 2017)

—Pre-DH: 10% (2016)

—**Post-DH: 54.41%** (Dec 2017)

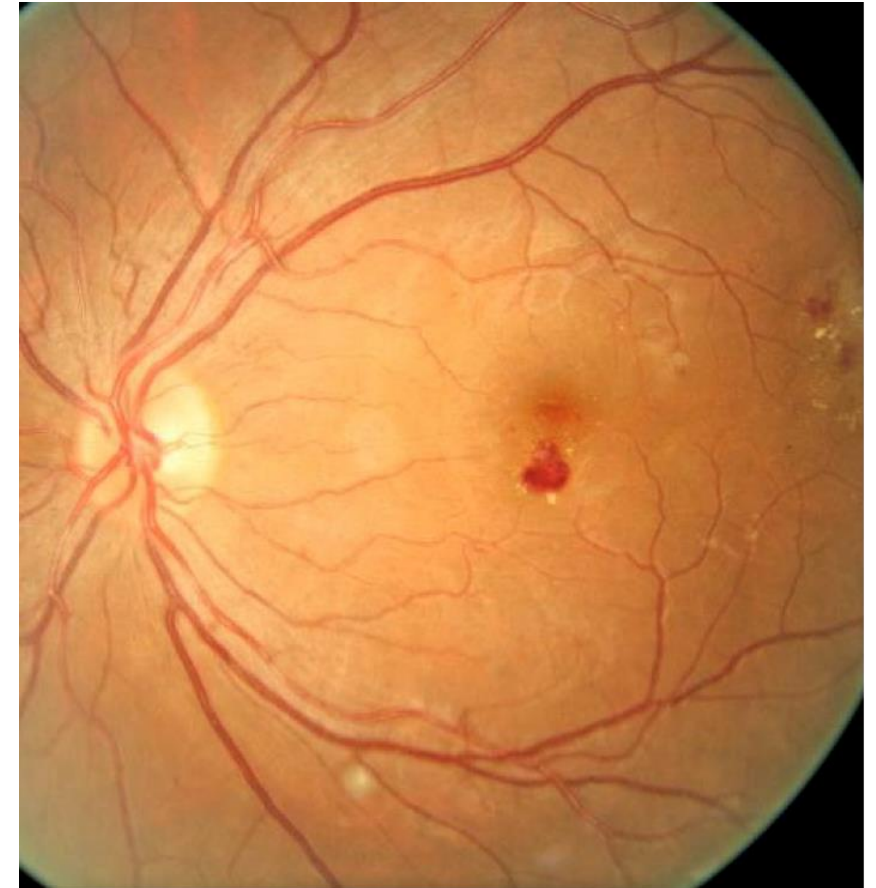
Telehealth at its best:

Case report of 37 year-old female with type 2 DM

- Gestational diabetes 12 yrs ago
- Converted to DM2 (x10 yrs)

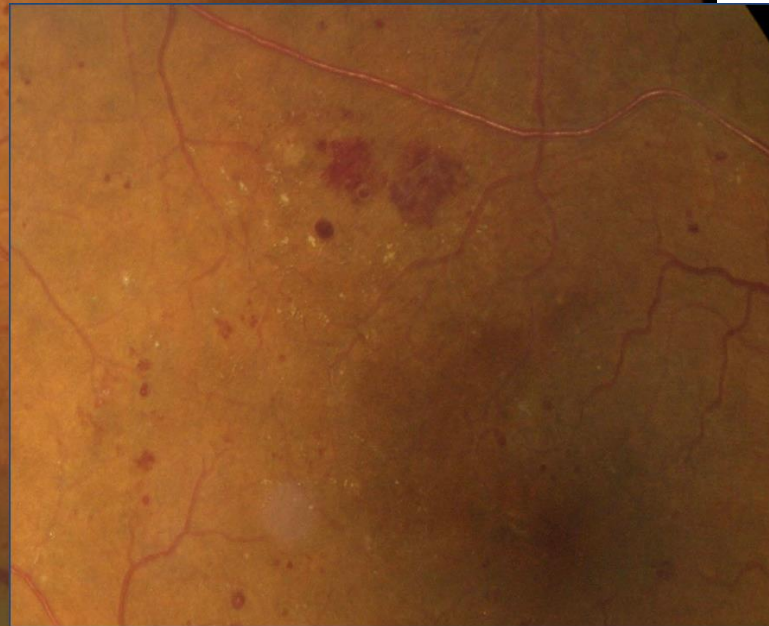
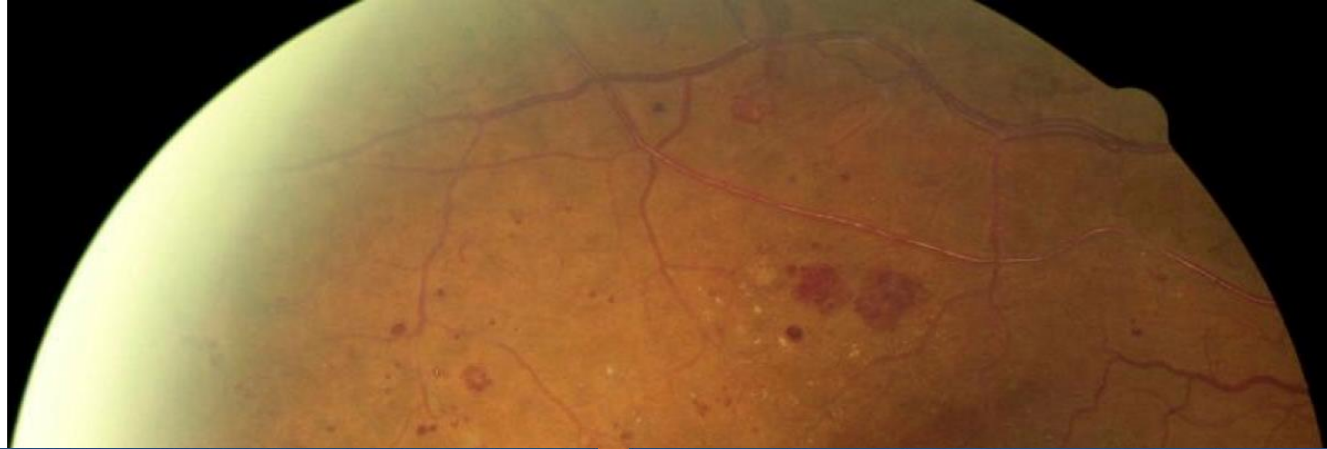
- Seen at Bay Area FQHC
 - Visit to PCP: A1c = 9.7%
 - Screened via DRS same day
 - Images reviewed 1 day later

- Referred for Clinically Significant Macular Edema
- Seen and treated by retinal specialist 4 days after point-of-care DRS



Telehealth at its best:

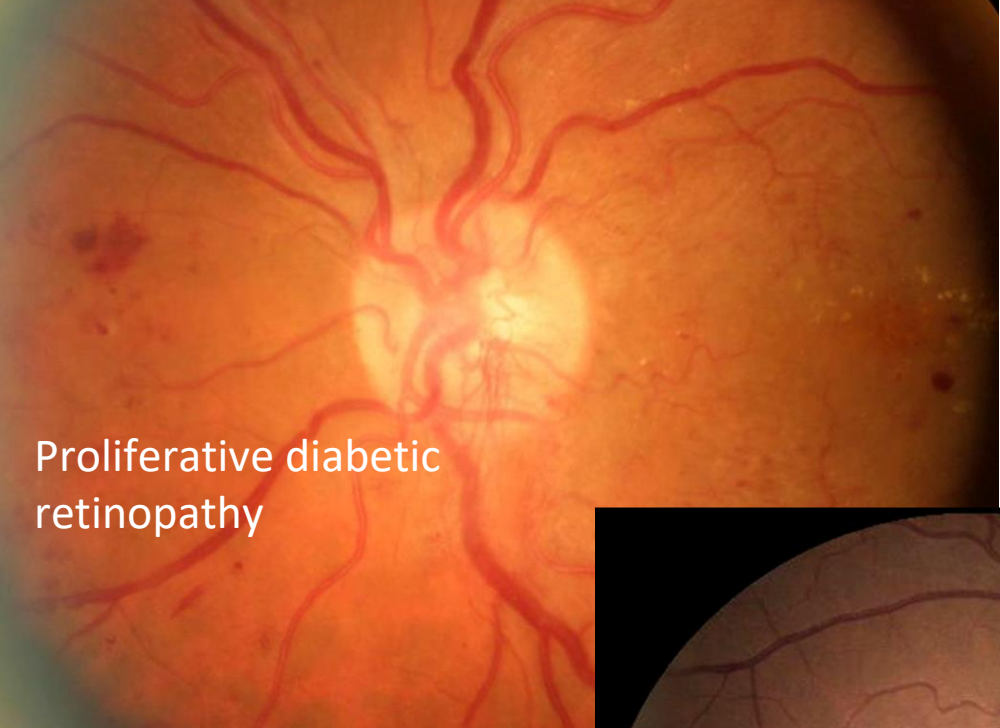
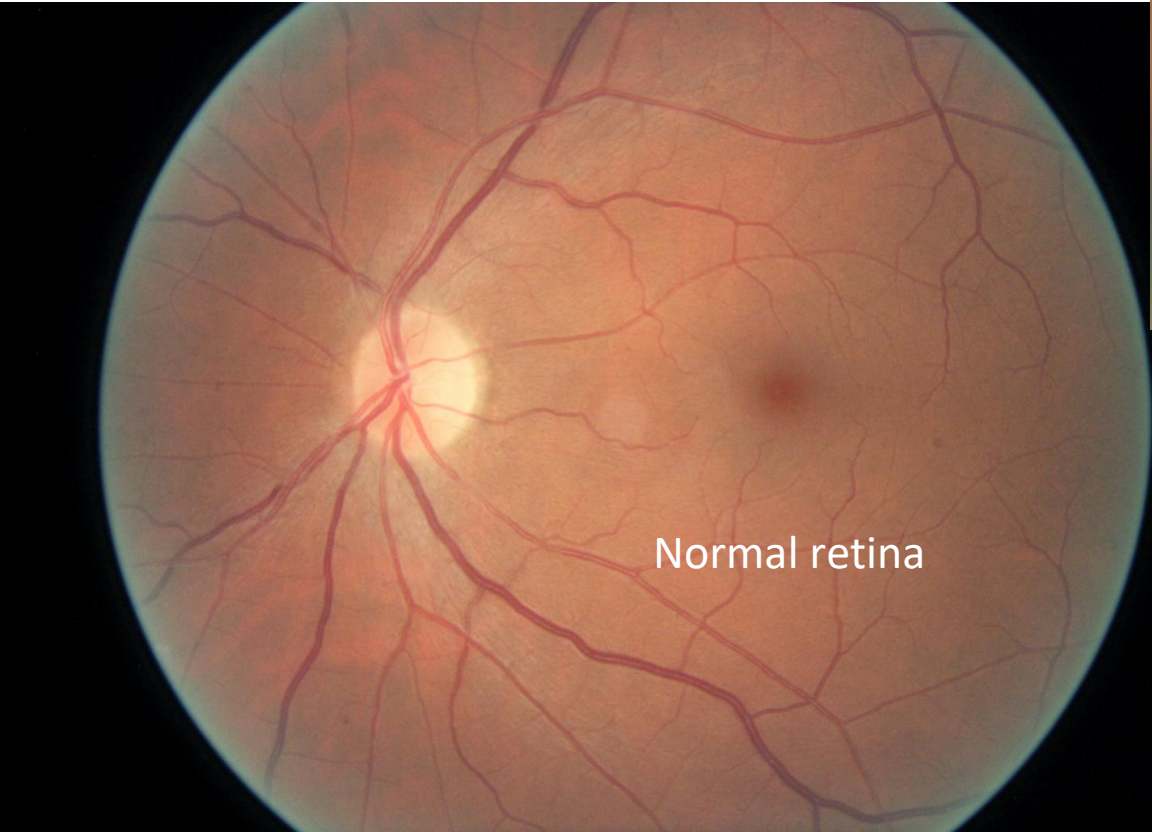
Case report of 60 year-old male with type 2 DM x 9yrs, A1c=9.7



Berkeley

Herbert Wertheim School of
Optometry & Vision Science

Patient education using retinal images



Basics of Implementing a DRS program

1) Camera acquisition:

Digital Health advises on retinal camera acquisition

- Camera selection and logistics consulting
- Purchases of new and refurbished camera models (including financing)
- Robotic cameras = easy learning curve
- Rentals available
- **We currently do not recommend *any* handheld cameras, due to poor quality photography and stability issues**



CrystalVue NFC600 robotic camera

2) Staff training and certification

To ensure quality photography and administrative support

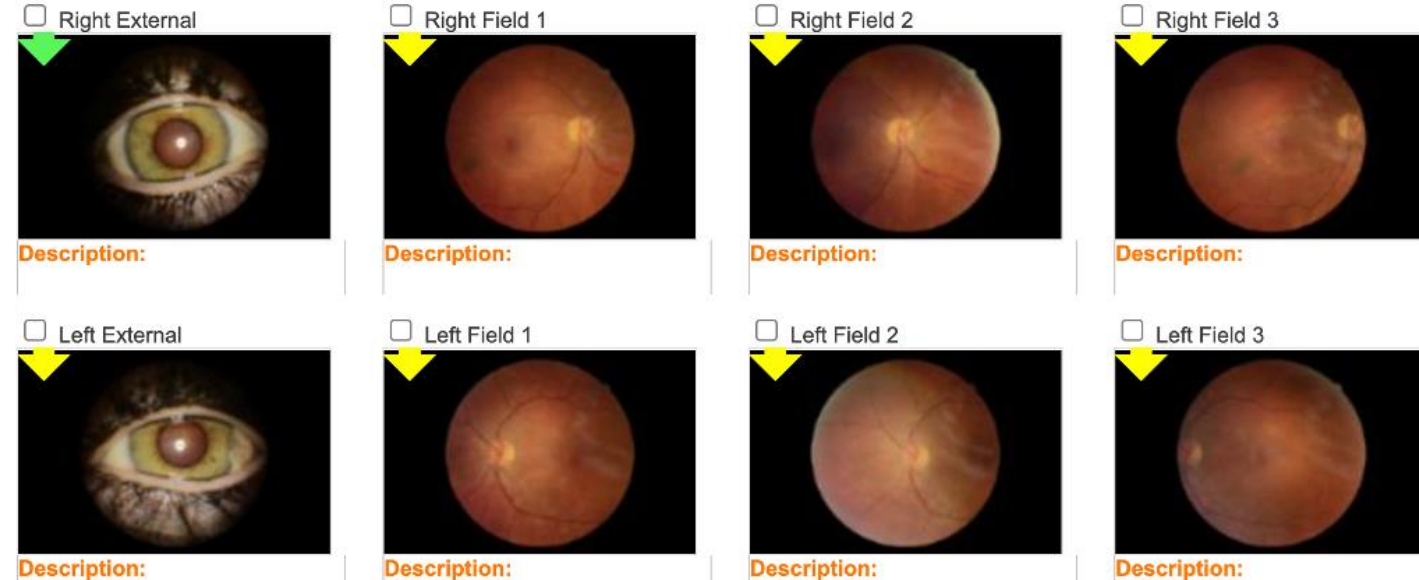
- Camera can be operated by any clinic staff (eg MA, nurse, provider)
- Staff trained by Digital Health (onsite or remote)
- After initial training, staff uploads practice cases for certification



retinal camera staff training

3) Patient images captured and uploaded to EyePACS portal

- Clinic staff capture retinal images of a patient using a digital retinal camera
 - *during/after* primary care visit
 - at appointment retinal screening hours
- Patient case/images evaluated online by consultant doctors
- Assessment and recommendations made, usually within 24 hours
- Report sent electronically to EMR and/or to PCP



Retinal Imaging Report

Site: NEVHC SF Cam - San Fernando patient

Patient: XXXXXXXX (DOB: XXXXXX) MRN: XXXXXX Payer: My Health LA (County) Coverage_ID: XXXXXXXXXXXXX

Retinal exam date: Jan 13, 2021
Retinal consult date: Jan 14, 2021
Date of this report: Jan 15, 2021
EyePACS case ID: XXXXXXXX

Diagnoses: No Apparent Diabetic Retinopathy (ICD-10: E10.9)

Recommendations: Return for retinal imaging within 1 year. Encourage regular eye care.

Case reviewed by: [Dr. Mark Sherstinsky, OD, MPH](#) - Tel: XXXXXXXXX on Jan 14, 2021 10:04:19 AM Digitally signed by:



Patient history: 39 year old Latin American Female

Diabetes duration: 5 years
Insulin dependent: Yes

Last retinal exam: 9 to 15 months
History of glaucoma: Not Sure

Image observations:

Right Eye: No apparent diabetic retinopathy

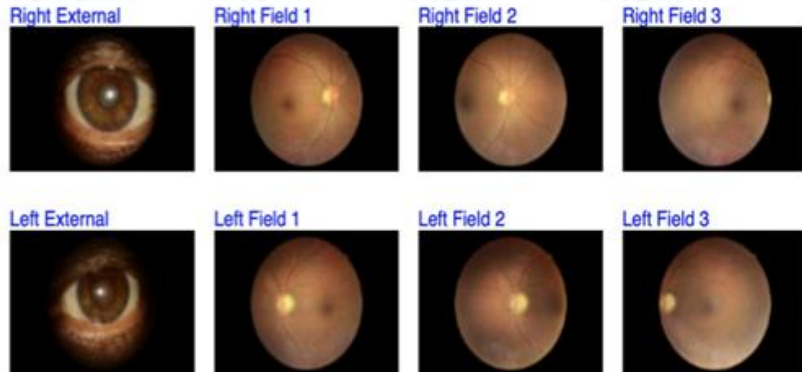
Left Eye: No apparent diabetic retinopathy

Image Observation Comments: Mild pigment disruption in each macula; ok to monitor annually, no referral needed.

Photographer: XXXXXXXXXXXX - Tel: XXXXXXXXX Jan 13, 2021

Image quality: Excellent. 8 images captured.

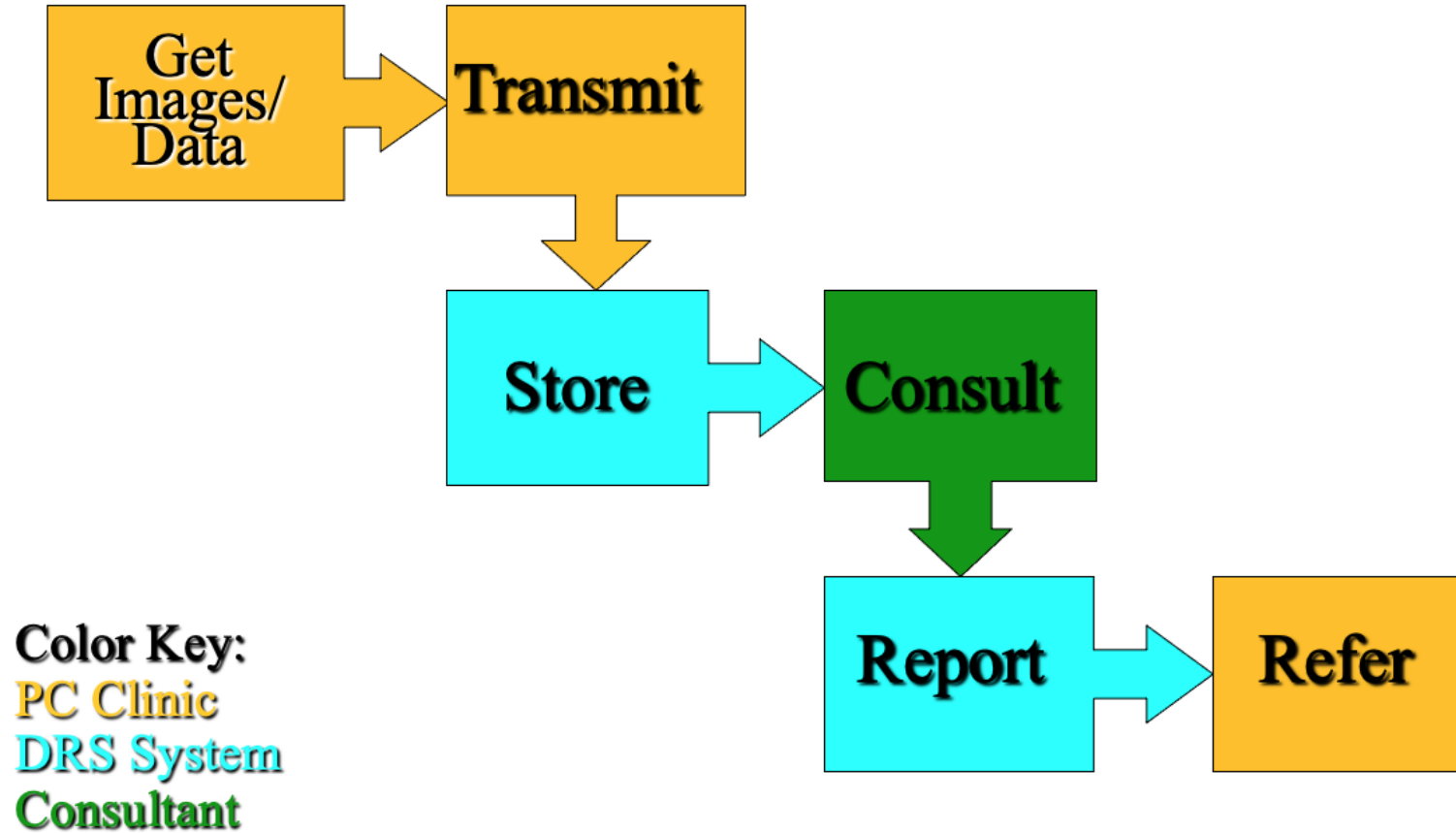
Full size digital images are available by request.



4) Case graded by eye care consultant

Sample EyePACS patient case report

General workflow and elements of store-and-forward DRS

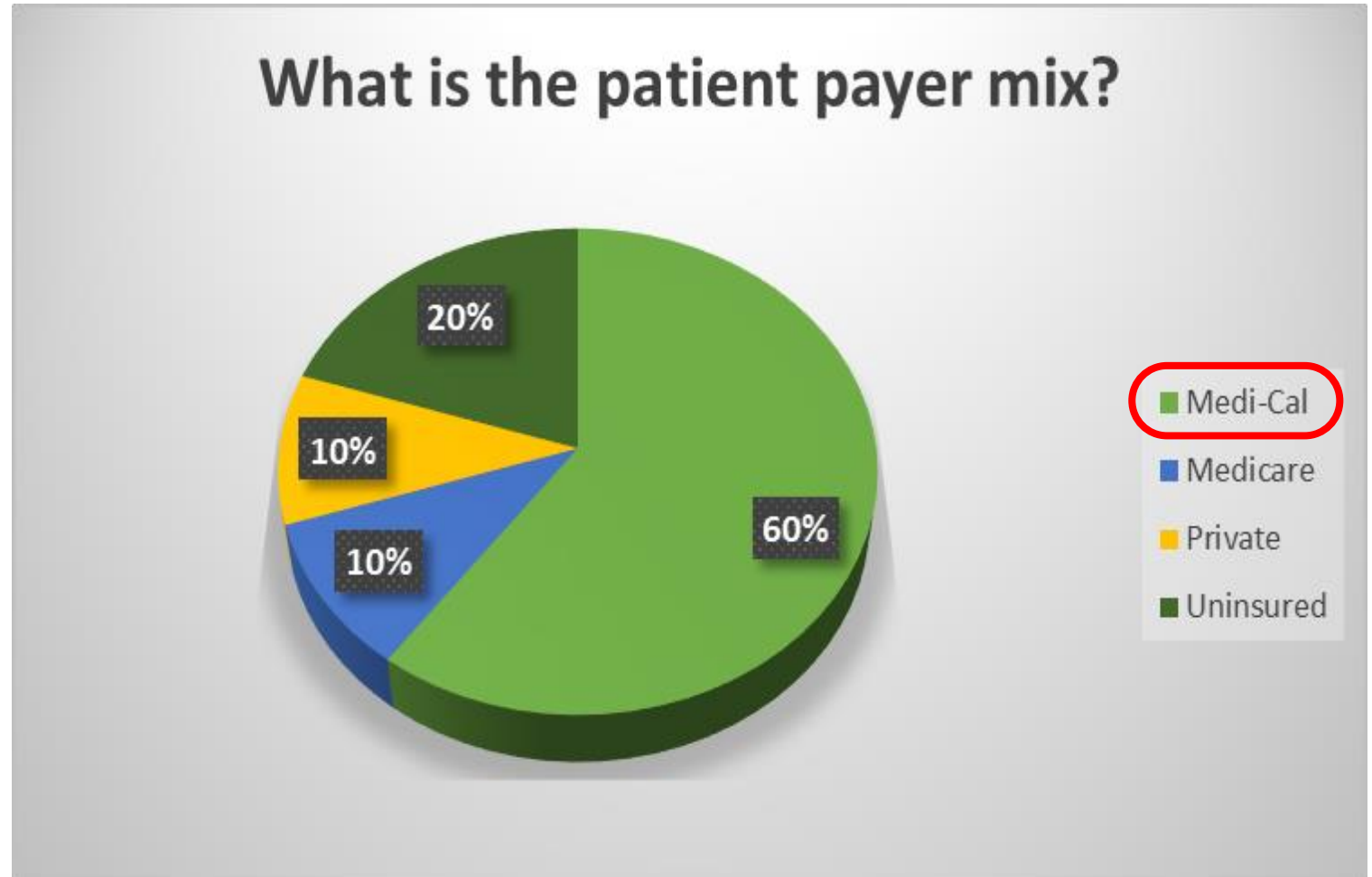


PPS Billing of Asynchronous Store-and-Forward DRS

FQHC Payer Breakdown

Over half of FQHC patients are Medi-Cal beneficiaries.

CPCA Optometry in FQHCs



Today's Discussion only applies to:

1. Medi-Cal
2. Medi-Cal Managed Care
3. Private Insurance (if allowed)

It does NOT include Medicare

The purpose of PPS billing is two-fold:

1. To allow for sustainable financial model to support DRS services.
2. To automatically register QOC measures for HEDIS without administrative follow up.

Medi-Cal Manual

Part 2 – Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

“Asynchronous Store and Forward Requirements

A patient may not be “established” on an asynchronous store and forward service, with the exception of HHMS.

Reimbursement is permitted for an established patient for teleophthalmology, teledermatology and teledentistry, and furnished by a billable provider at the distant site.

Note: Providers should note “Non-Covered Services” in this manual section.”

“Non-Covered Services

An e-consult is not a reimbursable telehealth service for FQHCs or RHCs.”

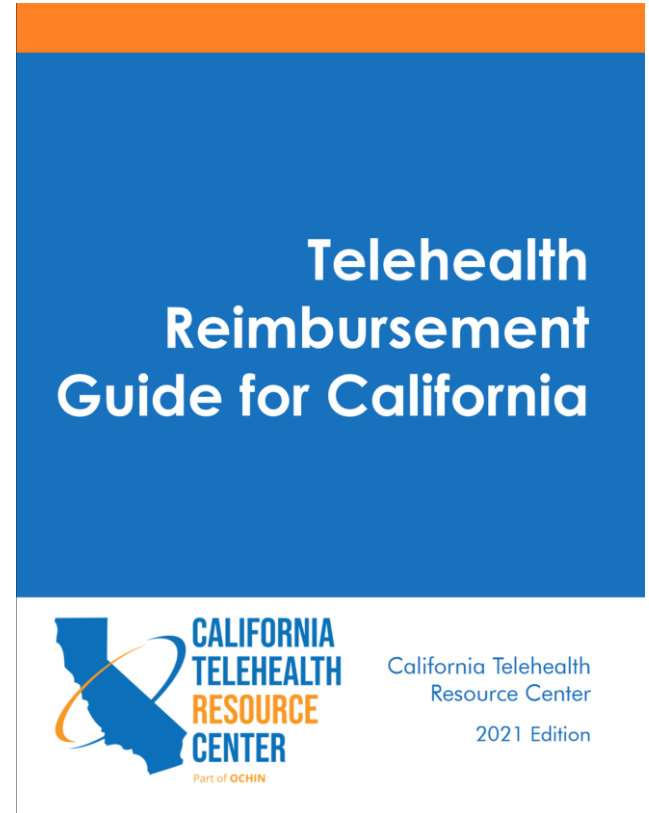
Excerpt from Page 35

Asynchronous Store and Forward:

An FQHC or RHC may bill at its PPS rate for store and forward ophthalmology, dermatology, and dentistry services provided to its established patient.

If the Distant Site is not an FQHC or RHC, the following requirements must be met for the Originating Site FQHC or RHC to be reimbursed at the PPS rate:

- a. Only one visit can be reimbursed at the PPS rate regardless of the services rendered at the Originating Site.
- b. The Originating Site FQHC or RHC must have an arrangement or current written agreement with the Distant Site to furnish the Store and Forward Services.
- c. The Originating Site FQHC or RHC must compensate the Distant Site for the Store and Forward Services furnished to its patients.
- d. The Distant Site must not directly bill Medi-Cal for the Store and Forward Services



DHCS Telehealth Advisory Workgroup meeting - February 22, 2022

16

Policy Area: Telehealth in FQHCs & RHCs

Proposed Approach

- Continue to reimburse FQHCs/RHCs at Prospective Payment System (PPS) rate for otherwise billable visits delivered via telehealth, including visits delivered via (1) video, (2) audio-only, and (3) store and forward.
- Continue exemption from site limitations for patient or provider.

Rationale

More closely **aligns reimbursement policy** across provider systems and **augments access to care**.

Current State

FQHCs/RHCs are reimbursed at the Prospective Payment System (PPS) rate for video, audio-only, and store and forward, and are not subject to site limitations for either patient or provider.

What it takes

- Credentialing of UC Berkeley Optometrists
 - With FQHC and then with your Payers
- Billing submission
 - CPT, ICD-10, and provider NPI all included on the report

CPT & HCPCS codes

1. 99213 (Office Visit CPT code); GQ modifier
2. G0467 (if necessary, HCPCS code for PPS reimbursement); GQ modifier
3. 2026F OR 2033F (CPT II)

ICD-10 codes

Diabetic Retinopathy Codes are automatically provided on EyePACS reports.

If no Apparent Diabetic Retinopathy: E10.9 (DM1) or E11.9 (DM2)

NPI – National Provider Identifier

Use of the NPI of a UC Berkeley Optometrist, credentialed with clinic for compliance.



Talk to Us Live!

**Please open the chat and
use it freely; we want to
hear from you!**



Contact Us Anytime:

Visit CalTRC.org/contact

OPEN FOR QUESTIONS, COMMENTS, AND DISCUSSION



Unmute and Join the
Conversation!

**Turn on your camera for
more interaction.**



Access National Resources

**Visit
TelehealthResourceCenter.org
for more info**

Stay Tuned for Our Next Event!



**CALIFORNIA
TELEHEALTH
RESOURCE
CENTER**
Part of OCHIN

Telehealth Implementation Workshop Office Hour Series

Begins April 19, 2022

- Four-Part Series
- Advanced Registration Required
- Limited Participant Spots Available



Thank You



www.caltrc.org

RETINOPATHY SCREENING PROGRAM AGREEMENT

THIS AGREEMENT ("**Agreement**") dated **Beginning date** ("**Effective Date**"), is by and between The Regents of the University of California, a California public corporation, acting on behalf of the University of California Berkeley Optometric Eye Center ("**UCBOEC**") and **Clinic Name** ("**Clinic**").

Background

- A. UCBOEC is a recognized provider of vision care and seeks to provide, in conjunction with Clinic, retinal image screening services especially for, but not limited to patients with diabetes ("**Retinal Screening**").
- B. Clinic is licensed to provide optometric services to the public and seeks to provide Retinal Screening to its patients using telemedicine techniques.
- C. Pursuant to an agreement with EyePACS LLC ("**EyePACS**"), UCBOEC is an authorized distributor of EyePACS' proprietary services which utilize specified hardware, EyePACS' web-based software, and the services of credentialed image reviewers to enable medical professionals and their personnel to capture ocular images of diabetic patients and transmit such images through EyePACS' secure Internet connection to a credentialed image reading network for evaluation and report (collectively, "**Services**").
- D. In connection with UCBOEC's appointment as a distributor of the Services, UCBOEC has been granted a non-exclusive license to use the Services and related EyePACS documentation and intellectual property, together with the right to sublicense such use.
- E. The parties to this Agreement intend to establish a non-exclusive relationship for use of the Services.

NOW, THEREFORE, intending to be legally bound, the parties agree as follows:

1. Grant of License.

1.1. Subject to the terms of this Agreement, UCBOEC hereby grants Clinic a limited, revocable, non-exclusive sub-license to access, display, and use the Services and any and all user manuals, handbooks, training material, specifications, trademarks and service marks and other written or electronic materials relating to the Services which are provided, or made available, by EyePACS ("**Documentation**") within the State of California during the Term of this Agreement.

1.2. In the exercise of its rights under this Agreement, Clinic will not state or imply that Clinic or Clinic's activities other than those required by this Agreement, are supported,

endorsed, or sponsored by UCBOEC.

1.3. Clinic will not alter, modify, dilute or otherwise misuse the Documentation, in connection with any use of the Services or Documentation without the prior written consent of EyePACS, LLC.

1.4. Clinic will, as reasonably requested by UCBOEC, acknowledge UCBOEC's support and continuing development of the diabetic retinopathy screening program using the EyePACS Services.

2. Term and Termination of Agreement.

This Agreement shall commence on the Effective Date and expire on **Termination date** ("**Term**"), with the option to renew for two (2) additional years by written amendment with an aggregate date through **Aggregate termination date**, unless sooner terminated by a party. This Agreement and all rights hereby granted may be revoked and terminated at any time by UCBOEC without cause on thirty (30) days' written notice to Clinic. Upon termination, Clinic will cease to use the Services and Documentation.

3. Equipment and Access.

3.1. Clinic will fulfill each of the technical requirements set forth in Exhibit A "Minimum Technical Requirements and Access Process."

3.2. For non-UCBOEC -owned cameras: Clinic will be responsible for acquiring, securing, and maintaining the retinal camera used to image patients.

3.3. For UCBOEC-owned cameras: UCBOEC will provide and maintain, with reasonable use, a retinal camera for use by Clinic for the purposes of retinal screening, to be placed within Clinic in a location agreed to by UCBOEC. Clinic will be responsible for securing the retinal camera, and will be responsible for any damages outside of normal wear and tear.

3.4. Clinic will identify to UCBOEC those individuals authorized to access the Services on behalf of Clinic ("**Authorized Users**") and provide a unique user ID for such Authorized Users (each, an "**Access ID**"). Access to the Services will be granted to Clinic as set forth in Exhibit A. All Authorized Users must have received training in the use of the Services. UCBOEC shall confirm that Clinic's Authorized Users have been trained in the use of the Services.

3.5. During the Term UCBOEC will have the right to collect eye images and related data resulting from Clinic's use of the Services and Documentation and to use such images and data, both during and after the Term. UCBOEC's use of such images and data will comply in all respects with the requirements of the Health Insurance Portability and Accountability Act

("HIPAA") relating to use of confidential patient information.

4. Services.

4.1. Clinic will schedule patients, obtain the patient's oral or written consent for telemedicine services, and record retinal images using a digital fundus camera operated by Authorized Users, and will make the resulting images available for UCBOEC by upload using the Services.

4.2. UCBOEC will provide to Clinic with a "Retinal Screening Report", which shall include reading, interpretation and, if necessary, referral within 5 business days after Clinic uploads each image. Each Retinal Screening Report will be prepared by a consultant, credentialed by EyePACS, LLC. UCBOEC will deliver Retinal Screening Reports to Clinic electronically through the Services and Documentation.

4.3. If the UCBOEC consultant preparing the Retinal Screening Report under Section 4.2 or any other UCBOEC employee or contractor is required to be credentialed or privileged at the site where the patient receives the Services, Clinic shall undertake, and shall be solely financially responsible for, such credentialing and privileging. UCBOEC shall cooperate, under Clinic's direction, with such credentialing and privileging matters but in no event shall UCBOEC be financially responsible for any such matters.

4.4. UCBOEC will validate the competency of their staff through credentialing and privileging per UCBOEC's credentialing and privileging policies and procedures (P&P) following a consistent credentialing and privileging process in accordance with applicable Federal, state, and local laws. UCBOEC ensures verification of staff licensure, certification, or registration through a credentialing process and verifies providers are competent and fit to perform the referred services as assessed through a privileging process.

4.5. Upon request by Clinic, UCBOEC may, if reasonably feasible, provide Clinic's staff with technical support for use of the Services through web meetings or by telephone. Neither UCBOEC nor EyePACS shall be responsible for technical support, or liable for breaches of warranty, for issues caused by any third party hardware, software or connections, including the Internet connection, or by Clinic's failure to maintain up-to-date anti-virus software. Clinic may contract with EyePACS directly for interface development and implementation. UCBOEC shall have no responsibility to Clinic with respect to interfaces.

4.6. UCBOEC is only providing consulting services and will not file insurance claims for this service. The clinic is responsible for filing insurance claims for the encounters.

5. Payment for Services

5.1 UCBOEC-owned cameras: Clinic will pay UCBOEC \$28.00 for each Retinal

Screening Report uploaded during the thirty (30) day period immediately following the Effective Date ("Initial Period"). Trainings will be provided in accordance with Section 5.3. Beginning after the Initial Period, UCBOEC will invoice Clinic a monthly rental fee of \$250.00, per camera.

5.1.1. This fee will cover the following services delivered by UCBOEC to Clinic: (a) training and certification of Clinic's Authorized Users as set forth in Section 5.3, (b) EyePACS web support, (c) technical and logistical support for maintaining a diabetic retinopathy screening program, and (d) quality control services at both the UCBOEC and Clinic levels.

5.1.2. Clinic will pay UCBOEC \$28.00 for each Retinal Screening Report. No portion of a fee shall be refundable upon termination of this Agreement by either party. Clinic will pay each invoice amount within fifteen (15) days after the date of the invoice with a check payable to "The Regents of the University of California."

5.2. Non-UCBOEC -owned cameras: Clinic will pay UCBOEC \$28.00 for each Retinal Screening Report uploaded during the thirty (30) day period immediately following the Effective Date ("Initial Period"). Trainings will be provided in accordance with Section 5.3.

5.2.1. This fee will cover the following services delivered by UCBOEC to Clinic: (a) training and certification of Clinic's Authorized Users as set forth in Section 5.3, (b) EyePACS web support, (c) technical and logistical support for maintaining a diabetic retinopathy screening program, and (d) quality control services at both the UCBOEC and Clinic levels.

5.2.2. Clinic will pay UCBOEC \$28.00 for each Retinal Screening Report. No portion of a fee shall be refundable upon termination of this Agreement by either party. Clinic will pay each invoice amount within fifteen (15) days after the date of the invoice with a check payable to "The Regents of the University of California."

5.3. The initial on-site training and certification of Authorized Users to operate the camera(s) will be provided at no cost to Clinic. Additional on-site trainings provided prior to the certification of Clinic's first Authorized User to operate the camera(s) will be invoiced to Clinic by UCBOEC at a fee of \$500.00 per training. Any additional trainings provided after the certification of Clinic's first EyePACS certified photographer (Authorized User) will be provided at no cost to Clinic.

6. University of California Name and Trademarks.

6.1. Clinic may use the UCBOEC name and logo subject to the terms of this Agreement and solely for the limited purposes of performing Clinic's obligations under this Agreement. Other than the rights granted herein and in Section 1.2, Clinic shall not use the name of the University of California, or any abbreviation thereof, or any name of which "University of California" is a part, or any trademarks of the University, in any commercial

context, such as may appear on products, in media (including web sites) and print advertisements in cases when such use may imply an endorsement or sponsorship of Clinic, its products or services.

6.2. All uses of the University's name and trademarks, therefore, must first receive prior written consent of The Regents of the University of California through the Office of Business Contracts and Brand Protection. This provision is in compliance with the State of California Education Code Section 92000.

7. Indemnification.

7.1. UCBOEC shall indemnify, defend and hold Clinic, its officers, agents, and employees, harmless from and against any and all liability, loss, expense, including reasonable attorney's fees, or claims for injury or damages arising out of the performance of this Agreement (including improper use or disclosure of patient protected health information) but only in proportion to and to the extent such liability, loss, expense, or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of UCBOEC, its officers, agents, or employees.

7.2. Clinic shall indemnify, defend and hold UCBOEC, its officers, agents, and employees, harmless from and against any and all liability, loss, expense, including reasonable attorney's fees, or claims for injury or damages arising out of the performance of this Agreement (including improper use or disclosure of patient protected health information) but only in proportion to and to the extent such liability, loss, expense, or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of Clinic, its officers, agents, or employees.

8. Insurance.

8.1. Professional Liability Insurance.

Each party will keep in full force and effect during the term of this Agreement a Professional Liability/Errors and Omissions Insurance Policy or, for UCBOEC, an equivalent funded program of self-insurance:

- | | |
|----------------------|-------------|
| a. Each Occurrence | \$1,000,000 |
| b. General Aggregate | \$3,000,000 |

8.2 General Liability Insurance.

Each party will keep in full force and effect during the term of this Agreement, Comprehensive or Commercial General Liability Insurance or for UCBOEC an equivalent funded program of

self-insurance as follows:

- a. Each Occurrence \$1,000,000
- b. Personal and Advertising Injury \$1,000,000
- c. General Aggregate * \$3,000,000
* (not applicable to comprehensive form)

8.3. Upon execution of this Agreement, each party shall file Certificate(s) of Insurance or self-insurance with the other party. Clinic’s Certificate of Insurance shall be delivered to UCBOEC’s representative, as specified in Section 18. Insurance certificate(s) for Commercial General Liability shall name the other party as an additional insured. Such provision shall apply in proportion to and to the extent of the negligent or intentional acts or omissions of the insuring party or of any person or persons under its direct supervision and control.

8.4. If insurance under this Section 8 is written on a claims-made form, following termination of the Agreement, coverage shall survive a period of three (3) years. Coverage shall coincide with the Effective Date of this Agreement. Thirty (30) days advance written notice shall be provided either party to the other of any modification, change, or cancellation of any of the above insurance coverage.

9. CONFIDENTIAL AND PATIENT-RELATED INFORMATION.

9.1. The parties acknowledge that in connection with their performance under this Agreement, each party may have access to and the use of “Confidential Information.” “Confidential Information” means all non-public information of EyePACS or of either Party disclosed hereunder, including without limitation, the EyePACS software, technical information, know-how, methodology, information relating to either Party’s business, including financial, promotional, sales, pricing, customer, supplier, and personnel information, financial statements, internal memoranda, reports, patient lists, and other materials or records of a proprietary nature. “Confidential Information” will not include information that: (i) is in or enters the public domain without breach of this Agreement; (ii) the receiving Party lawfully receives from a third party without restriction on disclosure and without breach of a nondisclosure obligation; (iii) the receiving Party knew prior to receiving such information from the disclosing Party; or (iv) develops independently without use of or resort to the other Party’s Confidential Information. To protect the Confidential Information, each party agrees that, subject to applicable law, neither it nor any of its employees or agents will, from and after the Effective Date of this Agreement and for so long as any such Confidential Information remains confidential, including beyond the expiration or termination of the Agreement, use another party’s Confidential Information or divulge such Confidential Information to any third party

(except in connection with the performance of duties contemplated hereunder), without first obtaining the prior written consent of the other party, which may be withheld at such party's sole discretion.

9.2. Any and all patient records, charts, protected health information, and other patient-related information created by or behalf of, or received from Clinic as a result of either party's performance under this Agreement (including Retinal Screening Reports) shall be and remain the property of Clinic. Both during and after the term of this Agreement, UCBOEC, or its agents, may inspect, duplicate, and/or obtain an electronic copy in a mutually agreed to format, any individual patient chart, record or other information to the extent necessary (i) to determine either party's respective responsibilities in the performance of this Agreement; (ii) to meet professional responsibilities to patient(s); (iii) to assist in the defense of any malpractice or similar claim to which such chart or record may be pertinent; or (iv) to comply with applicable legal and regulatory requirements, provided that such inspection, duplication or receipt is permitted and conducted in accordance with the applicable legal requirements and pursuant to commonly accepted standards of patient confidentiality.

9.3. Notwithstanding the foregoing, the use, as well as any disclosure, of patient records and other records prepared or maintained by either party containing any patient's protected health information or other information identifying a patient in any way, shall be made in compliance with the relevant provisions of all applicable federal and state requirements, including without limitation such requirements set forth in the following laws, as such are amended from time to time: (i) the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH Act") and the regulations promulgated pursuant thereto establishing standards for privacy of individually identifiable health information and security standards for protecting electronic protected health information, contained in title 45 Code of Federal Regulations (CFR) parts 160 and 164, and any other applicable regulations promulgated pursuant to such legislation.

10. No Requirement For Referrals.

Nothing in this Agreement or in any other written or oral agreement between or among UCBOEC, Clinic or Clinic's staff, nor any consideration offered or paid in connection with this Agreement, contemplates or requires the admission or referral of any patient to UCBOEC or Clinic. This Agreement is not intended to influence Clinic's, Clinic's staff, or UCBOEC's judgment in choosing the medical or other clinical facility appropriate for the proper care and treatment of any patients.

11. Business Associate Agreement.

The Parties have entered into a Business Associate Agreement, attached hereto as Exhibit B (the "BAA").

12. Limitation of Liability.

12.1. SUBJECT TO SECTION 12.2 BELOW, NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY CONSEQUENTIAL, SPECIAL, EXEMPLARY, OR PUNITIVE DAMAGES (INCLUDING DAMAGES FOR LOSS OF REVENUE, AND/OR PROFITS), WHETHER FORESEEABLE OR UNFORESEEABLE, ARISING OUT OF THIS AGREEMENT REGARDLESS OF WHETHER THE LIABILITY IS BASED ON BREACH OF CONTRACT, TORT, STRICT LIABILITY, BREACH OF WARRANTIES OR OTHERWISE, AND EVEN IF THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF THOSE DAMAGES.

12.2. THE LIMITATIONS ON LIABILITY SET FORTH IN SECTION 12.1 DO NOT APPLY TO ANY CLAIM FOR INDEMNITY BY EITHER PARTY ARISING OUT OF A THIRD PARTY'S CLAIM, OR TO LIABILITY ARISING FROM: (I) A BREACH OF A PARTY'S OBLIGATIONS UNDER SECTION 9 (CONFIDENTIALITY) OR UNDER THE BAA; (II) ANY INFRINGEMENT, MISUSE OR MISAPPROPRIATION OF ANY INTELLECTUAL PROPERTY RIGHTS; OR (III) FRAUD.

13. Amendments.

This Agreement may be amended or modified only by means of a written document signed by both Parties.

14. Waiver.

No waiver by either party hereto of any breach of any of the provisions herein set forth shall be deemed a waiver as to any subsequent and/or similar breach.

15. Binding Effect.

This Agreement shall bind and inure to the benefit of the parties hereto and their respective successors and assigns.

16. Relationship.

This Agreement does not constitute and shall not be construed to constitute a partnership or joint venture between UCBOEC and Clinic, nor a franchise agreement between UCBOEC and Clinic. Licensee shall have no right to obligate or bind UCBOEC in any manner whatsoever, and nothing contained in this Agreement shall give or is intended to give any rights of any kind to third persons. Neither party hereto is an agent, employee or servant of the other party.

17. Governing Law.

This Agreement shall be construed in accordance with the laws of the State of California, excluding its conflict of laws rules.

18. Notices.

Except as otherwise provided in this Agreement, any notice required by this Agreement shall be deemed to have been properly received when delivered (a) in person, (b) when mailed by registered first class mail to the addressees given below, or such other addressees as may be designated from time to time, (c) by facsimile transmission to the party's facsimile number, with a transmission report indicating transmission without error or (d) by email with a "delivery receipt" and/or "read receipt" to the email address provided by the parties during the term of this Agreement :

If to UCBOEC:

Optometry Eye Center, Minor Hall
Attention: Director of UC Berkeley Digital Health
University of California Berkeley
Berkeley, CA 94720
Facsimile: 510-643-1874
Email: ucb.digital.health@berkeley.edu

If to Clinic:

Clinic Name
Attention:
Clinic Address
Facsimile:
Email:

19. FQHC Compliance

19.1 Clinic may be or may during the Term become, a federally qualified health center ("FQHC") that will monitor and provide oversight over contract performance for the Term of this Agreement, in accordance with the HRSA compliance manual, in which case UCBOEC shall comply with the obligations set forth in this Section 19. The parties agree that such monitoring may include:

1. Reviewing a list of Clinic's patients seen by UCBOEC monthly or quarterly, or as determined necessary by the CMO;
2. Ensuring reports are received in accordance with Section 4.2 above;
3. Obtaining Clinic, UCBOEC, and Staff feedback on the services provided by UCBOEC;
4. Reviewing patient complaints regarding services provided by UCBOEC and/or conduct a patient survey, if deemed necessary;
5. Ensuring invoices received from UCBOEC reflect only services provided and authorized by Clinic; and
6. Securing any other required information from UCBOEC relating to the patients

care in order to provide the highest quality of care, without repeating any unnecessary test or services already provided by the UCBOEC.

7. Making the referred service available on a sliding fee discount or payment schedule for eligible FQHC health center patients at or below 200% of the Federal Poverty Guideline.

19.2. In addition, Clinic’s COO, CFO and/or Compliance Officer may audit relevant records as determined necessary to monitor this Agreement with UCBOEC. UCBOEC will make all relevant records relating to the Agreement available for audit upon request and comply with the record retention requirements section 45 CFR 75.361 of the code of federal regulations.

19.3 UCBOEC will comply with Clinic’s property management requirements, which includes a management system for equipment purchased with Federal funds in accordance with section 45 CFR 74.34, when applicable. Currently such compliance is not applicable and Clinic will notify UCBOEC if at any point this compliance becomes applicable.

19.4 Through the Federal Tort Claims Act (FTCA), eligible HRSA-supported health centers may be granted medical malpractice liability protection with the Federal government acting as their primary insurer. Clinic may provide evidence of deemed status as an alternative to Section 8.1, Professional Liability Insurance.

20. Counterparts.

The parties may execute this Agreement in any number of counterparts. Each counterpart will be deemed an original and all counterparts will constitute one agreement binding on both parties. Facsimile or electronically authenticated signatures will be considered binding for all purposes.

IN WITNESS WHEREOF, the Parties have signed this Agreement as of the date first above written.

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

By: _____
Michele Huff, Director

Clinic: **Clinic Name**

By: _____

SIGNATURE

Exhibit A

Minimum Technical Requirements and Access Process

1. Minimum Technical Requirements for Implementing Diabetic Retinopathy Screening with EyePACS:

Summary:

1. Connectivity:
 - i. Allow upload of image files to trusted Internet site
 - ii. Allow SSL at 128 bit encryption in web browser
 - iii. 256 kb/sec minimum connection to Internet
2. Direct telephone communication at the camera available for service calls, troubleshooting, and patient consults (cell phone is acceptable).
3. Four plugs for imaging devices and computer. Maximum electrical requirement for all devices: 5 Amps
4. The room must be able to be darkened completely.
5. Ability to print out Retinopathy Screening reports, or to import results directly into HER.
6. Computers for the program must meet these minimum specifications:
 1. CPU: 2 GHz
 2. Hard Drive: 40 Gb - 5400 rpm
 3. RAM: 512 MB
 4. Two standard USB2 inputs
 5. Video Card: 128 Mb vRAM; supports 1152 X 864 resolution in 24-bit color
 6. 10Mb/SNIC
 7. Latest virus protection and operating system updates (Windows, Mac, or Unix)
 8. Monitor: 15" Flat screen or flat panel; 60 Hz refresh rate.
7. Retinal camera capable of producing a minimum of 5MP resolution images.

2. Access Process for Diabetic Retinopathy Screening with EyePACS:

1. Clinic must identify Authorized Users for EyePACS access.
2. Clinic must provide UCBOEC with Authorized User's full name and e-mail address.
3. UCBOEC will initiate an invitation e-mail through EyePACS that will be sent to the Authorized User's e-mail address.
4. The Authorized User will click on the link provided in the invitation e-mail, which will direct Authorized User to EyePACS through their web browser to create a username and password.
5. It is the Clinic's sole responsibility to notify UCBOEC in the event that the Authorized User is no longer authorized for EyePACS use. Upon notification, UCBOEC will immediately de-activate said User's account.

EXHIBIT B
BUSINESS ASSOCIATE AGREEMENT

This HIPAA Business Associate Agreement ("BA AGREEMENT") supplements and is made a part of the Retinopathy Screening Agreement(s) ("Agreement") entered into by and between The Regents of the University of California, a California constitutional corporation, on behalf its University of California, Berkeley, School of Optometry ("BUSINESS ASSOCIATE") and **CLINIC NAME** ("CLINIC") and is effective as of **BEGINNING DATE** ("Effective Date"). This BA AGREEMENT supersedes and replaces all prior business associate agreements between BUSINESS ASSOCIATE and CLINIC with respect to Agreement.

RECITALS

- A. CLINIC and BUSINESS ASSOCIATE desire to protect the privacy and provide for the security of Protected Health Information (as that term is defined herein) used by or disclosed to BUSINESS ASSOCIATE in compliance with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the regulations promulgated thereunder by the U.S. Department of Health and Human Services (45 C.F.R. Parts 160, 162 and 164, the "HIPAA Regulations"), and the Health Information Technology for Economic and Clinical Health Act of 2009 (the "HITECH Act"). The purpose of this BA AGREEMENT is to satisfy certain standards and requirements of HIPAA, the HIPAA Regulations, including 45 C.F.R. §§ 164.314(a) and 164.504(e), and the HITECH Act, including Subtitle D, part 1, each as in effect on the Effective Date.
- B. Pursuant to the Agreement, BUSINESS ASSOCIATE will provide services to CLINIC, involving access to, receipt of, and the use or disclosure of Protected Health Information in the course of providing such services.
- C. CLINIC wishes to disclose to BUSINESS ASSOCIATE certain information, some of which may constitute Protected Health Information.

Therefore, intending to be legally bound hereby, the parties agree as follows:

1. **EFFECT OF AGREEMENT.** To the extent that the terms of the Agreement (inclusive of all subsequent agreements between CLINIC and BUSINESS ASSOCIATE) are inconsistent with the terms of this BA AGREEMENT, the terms of this BA AGREEMENT shall control, but only to the extent necessary to satisfy the purposes of this BA AGREEMENT.

2. **DEFINITIONS.**

2.1 "Breach," solely for purposes of Section 3.6 of this BA AGREEMENT (including its subsections), shall have the meaning given to such term in 45 C.F.R. §164.402 (including all of its subsections) of the Regulations; with respect to all other uses of the word "breach" in this

Agreement (e.g., section 4), the word has its ordinary contract meaning.

2.2 "Electronic Health Record" shall have the meaning given to such term in Section 13400(5) of the HITECH Act.

2.3 "Electronic PHI" shall have the meaning given to such term in 45 C.F.R. § 160.103, but limited to the information created or received by BUSINESS ASSOCIATE from or on behalf of CLINIC.

2.4 "Information System" shall have the meaning given to such term in 45 C.F.R. § 164.304.

2.6 "Protected Health Information" ("PHI") shall have the meaning given to such term in 45 C.F.R. § 160.103, but limited to the information created or received by BUSINESS ASSOCIATE from or on behalf of CLINIC.

2.7 "Required By Law" shall have the meaning given to such term in 45 C.F.R. § 164.103.

2.8 "Secretary" means the Secretary, Department of Health and Human Services, or his or her designee.

2.9 "Security Incident" shall have the meaning given to such term in 45 C.F.R. § 164.304.

2.10 "Unsecured PHI" shall have the meaning given to such term in 45 C.F.R. § 164.402, but limited to the information created or received by BUSINESS ASSOCIATE from or on behalf of CLINIC.

2.11 "Encryption" shall have the meaning given to such term in 45 C.F.R. § 164.304.

3. RESPONSIBILITIES OF BUSINESS ASSOCIATE.

3.1 Permitted Uses and Disclosures of PHI. Except as otherwise required or permitted by this BA AGREEMENT, BUSINESS ASSOCIATE may use or disclose PHI solely for the purpose of performing services, a function or activity for or on behalf of the CLINIC in connection with the Agreement or any subsequent agreements between BUSINESS ASSOCIATE and the CLINIC, provided that such use or disclosure would not violate Subpart E of 45 C.F.R. Part 164 if done by the CLINIC, including the minimum necessary standard set forth at 45 C.F.R. § 164.502(b). To the extent the BUSINESS ASSOCIATE carries out one or more of CLINIC's obligation(s) under Subpart E of 45 C.F.R. Part 164, BUSINESS ASSOCIATE must comply with the requirements of Subpart E that apply to the CLINIC in the performance of such obligation(s).

3.1.1 Documentation of Disclosures. With respect to any disclosures of PHI by BUSINESS ASSOCIATE as permitted under section 3.1, BUSINESS ASSOCIATE shall document such disclosures including, but not limited to, the date of the disclosure, the name and, if known, the address of the recipient of the disclosure, a brief description of the PHI disclosed, and the purpose of the disclosure, to the extent that such disclosures are subject to the accounting of disclosures requirements at 45 C.F.R. § 164.528.

3.2 Other Permitted Uses and Disclosures of PHI. BUSINESS ASSOCIATE may use PHI (i) for the proper management and administration of BUSINESS ASSOCIATE's business, (ii) to provide data aggregation services relating to the health care operations of CLINIC, or (iii) to carry out BUSINESS ASSOCIATE's legal responsibilities, subject to the limitation in section 3.3, below. BUSINESS ASSOCIATE also may disclose PHI for the proper management and administration of BUSINESS ASSOCIATE or to carry out the legal responsibilities of BUSINESS ASSOCIATE if the disclosure is Required By Law, or if BUSINESS ASSOCIATE obtains reasonable assurances from the person to whom the PHI is being disclosed that the PHI will be held confidentially and used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and the person notifies the BUSINESS ASSOCIATE of any instances of which it is aware in which the confidentiality of the information has been breached.

3.3 Nondisclosure of PHI. BUSINESS ASSOCIATE is not authorized and shall not use or further disclose CLINIC's PHI other than as permitted or required under this BA AGREEMENT or as Required By Law.

3.3.1 Disclosures Required by Law. In the event BUSINESS ASSOCIATE is Required By Law to disclose PHI, BUSINESS ASSOCIATE shall promptly notify CLINIC of such requirement. To the extent reasonably practicable, BUSINESS ASSOCIATE shall make good faith efforts to give CLINIC an opportunity to oppose such disclosure or take other appropriate action before BUSINESS ASSOCIATE discloses the PHI.

3.3.2 Legal Process. In the event BUSINESS ASSOCIATE is served with legal process or a request from a governmental agency that may potentially require the disclosure of PHI, and if in BUSINESS ASSOCIATE'S sole judgment BUSINESS ASSOCIATE is permitted to do so, BUSINESS ASSOCIATE shall make good faith efforts to promptly, and if reasonably practicable within three (3) business days of its receipt of such legal process or request, notify CLINIC.

3.4 Prohibition on Sale of PHI for Remuneration. BUSINESS ASSOCIATE will not sell PHI or receive any direct or indirect remuneration in exchange for PHI except as permitted by this BA AGREEMENT and applicable law.

3.5 Security Standards. BUSINESS ASSOCIATE agrees to use appropriate safeguards to

prevent use or disclosure of the Protected Health Information other than as provided for by this BA AGREEMENT. In addition, BUSINESS ASSOCIATE agrees to comply with applicable requirements of the HIPAA Security Rule at 45 C.F.R. Part 164 Subpart C.

3.6 Notification of Breaches and Security Incidents.

3.6.1 Following BUSINESS ASSOCIATE's discovery of a Breach of Unsecured PHI, BUSINESS ASSOCIATE will notify the CLINIC of such Breach in accordance with 45 C.F.R. §§ 164.410 and 164.412.

3.6.2 BUSINESS ASSOCIATE agrees to report to the CLINIC any Security Incident respecting Electronic PHI in BUSINESS ASSOCIATE's possession or control, of which BUSINESS ASSOCIATE becomes aware, except that this BA AGREEMENT shall hereby serve as notice, and no further reporting shall be required, of the regular occurrence of unsuccessful attempts at unauthorized access, use, disclosure, modification, or destruction of Electronic PHI or the unsuccessful attempt to interfere with system operations in an information system containing Electronic PHI.

3.6.3 BUSINESS ASSOCIATE agrees to report to the CLINIC any use or disclosure of PHI not provided for by this BA AGREEMENT of which BUSINESS ASSOCIATE becomes aware.

3.7 BUSINESS ASSOCIATE agrees to mitigate, to the extent practicable, any harmful effect that is known to BUSINESS ASSOCIATE of a use or disclosure of PHI by BUSINESS ASSOCIATE in violation of the requirements of this BA AGREEMENT.

3.8 Regulatory Compliance. BUSINESS ASSOCIATE shall make its internal practices, books and records relating to the use, disclosure or security of PHI received from CLINIC (or created or received by BUSINESS ASSOCIATE on behalf of CLINIC) available to the Secretary, for purposes of the Secretary determining CLINIC's compliance with the HIPAA Regulations.

3.9 Rights of Individuals.

3.9.1 If BUSINESS ASSOCIATE maintains PHI in a Designated Record Set for the CLINIC, BUSINESS ASSOCIATE agrees to make any amendment(s) to PHI in a Designated Record Set that the CLINIC directs or agrees to pursuant to 45 C.F.R. § 164.526 at the request of the CLINIC or an Individual, and in the time and manner that reasonably permits CLINIC to comply with 45 C.F.R. § 164.526.

3.9.2 Individual's Request for an Accounting of Disclosures of PHI. Within a reasonable time after receipt of a written request, BUSINESS ASSOCIATE shall make available to CLINIC, or, if authorized in writing by CLINIC, to the subject of the PHI, such information

maintained by BUSINESS ASSOCIATE or its agents as may be required for CLINIC to respond to an Individual's request that the CLINIC provide an accounting of disclosures under 45 C.F.R. § 164.528.

3.9.3 If BUSINESS ASSOCIATE maintains PHI in a Designated Record Set for the CLINIC, BUSINESS ASSOCIATE agrees to provide access, at the request of the CLINIC, to PHI in a Designated Record Set to the CLINIC or, as directed by the CLINIC, to an Individual in a time and manner that reasonably permits CLINIC to meet the requirements under 45 C.F.R. § 164.524.

3.10 BUSINESS ASSOCIATE agrees to ensure that any agent, including a subcontractor, to whom it provides PHI received from, or created or received by BUSINESS ASSOCIATE on behalf of the CLINIC agrees to the same or similar restrictions and conditions that apply through this BA AGREEMENT to BUSINESS ASSOCIATE with respect to such information and to comply with applicable requirements of the HIPAA Security Rule at 45 C.F.R. Part 164 Subpart C.

4. RESPONSIBILITIES OF CLINIC

4.1 Limitations in Notice of Privacy Practices. CLINIC shall notify BUSINESS ASSOCIATE of any limitation(s) in the notice of privacy practices of CLINIC under 45 C.F.R. § 164.520, to the extent that such limitation may affect BUSINESS ASSOCIATE's use or disclosure of PHI.

4.2 Changes to Individual's Permission. CLINIC shall notify BUSINESS ASSOCIATE of any changes in, or revocation of, the permission by an Individual to use or disclose his or her PHI, to the extent that such changes may affect BUSINESS ASSOCIATE's use or disclosure of PHI.

4.3 Agreed Upon Restrictions. CLINIC shall notify BUSINESS ASSOCIATE of any restriction on the use or disclosure of PHI that CLINIC has agreed to or is required to abide by under 45 C.F.R. § 164.522, to the extent that such restriction may affect BUSINESS ASSOCIATE's use or disclosure of PHI.

4.4 No Impermissible Requests. CLINIC shall not request or cause BUSINESS ASSOCIATE to use or disclose PHI in any manner that would not be permissible under the Privacy Rule at 45 C.F.R. Part 164 Subpart E if done by CLINIC, except for uses or disclosures set forth in Sections 3.2 above.

5. TERMINATION AND OTHER REMEDIES.

5.1 Termination for Cause.

5.1.1 By The CLINIC. Upon the CLINIC's knowledge of a material breach by

BUSINESS ASSOCIATE of this BA AGREEMENT, the CLINIC may:

5.1.1.1 Provide a reasonable opportunity for BUSINESS ASSOCIATE to cure the material breach or end the material violation and if BUSINESS ASSOCIATE does not cure the material breach or end the material violation within a reasonable time, the CLINIC may terminate this BA AGREEMENT and the provisions of the Agreement that require or permit BUSINESS ASSOCIATE to access Protected Health Information; or

5.1.1.2 If BUSINESS ASSOCIATE has breached a material term of this BA AGREEMENT and cure is not possible, immediately terminate this BA AGREEMENT and the provisions of the Agreement that require or permit BUSINESS ASSOCIATE to access Protected Health Information.

5.1.2 By BUSINESS ASSOCIATE. Upon BUSINESS ASSOCIATE's knowledge of a material breach by the CLINIC of this BA AGREEMENT, BUSINESS ASSOCIATE may:

5.1.2.1 Provide a reasonable opportunity for the CLINIC to cure the material breach or end the material violation and if the CLINIC does not cure the material breach or end the material violation within a reasonable time, BUSINESS ASSOCIATE may terminate this BA AGREEMENT and the provisions of the Agreement that require or permit BUSINESS ASSOCIATE to access Protected Health Information; or If the CLINIC has breached a material term of this BA AGREEMENT and cure is not possible, immediately terminate this BA AGREEMENT and the provisions of the Agreement that require or permit BUSINESS ASSOCIATE to access Protected Health Information.

5.2 Effect of Termination.

5.2.1 Except as provided in 5.2.2, upon termination of this BA AGREEMENT, for any reason, BUSINESS ASSOCIATE will return or destroy all PHI received from the CLINIC, or created or received by BUSINESS ASSOCIATE on behalf of the CLINIC. This provision applies to PHI that is in the possession of subcontractors or agents of BUSINESS ASSOCIATE. BUSINESS ASSOCIATE will retain no copies of the PHI.

5.2.2 In the event that BUSINESS ASSOCIATE determines that returning or destroying the PHI is infeasible, BUSINESS ASSOCIATE will provide to the CLINIC notification of the conditions that make return or destruction infeasible. In such event, BUSINESS ASSOCIATE will extend the protections of this BA AGREEMENT to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as BUSINESS ASSOCIATE maintains such PHI.

6. MISCELLANEOUS PROVISIONS.

6.1 Independent Contractor. BUSINESS ASSOCIATE is an independent contractor and nothing in this BA AGREEMENT is intended to create or imply an agency or employment relationship between CLINIC and BUSINESS ASSOCIATE.

6.2 No Third-Party Beneficiaries. Nothing express or implied in this BA AGREEMENT is intended to confer, nor shall anything herein confer, any rights, remedies, obligations or liabilities whatsoever upon any person or entity other than CLINIC, BUSINESS ASSOCIATE and their respective agents, successors or assigns.

6.3 Number. Where the context admits, words in the plural include the singular, and the singular includes the plural.

6.4 Survival. The respective rights and obligations of BUSINESS ASSOCIATE and the CLINIC under Section 4 of this BA AGREEMENT survive the termination of this BA AGREEMENT.

6.5 Notices. Any notices to be given to either party shall be made via U.S. Mail or express courier to the address given below and/or via facsimile to the facsimile telephone numbers listed below and or email, each with a confirmation of transmission.

If to CLINIC:

Clinic Name

Attention:

Clinic Address

Facsimile:

Email:

If to BUSINESS ASSOCIATE:

Optometry Eye Center, Minor Hall
Attention: Director of UC Berkeley Digital Health
University of California Berkeley
Berkeley, CA 94720
Facsimile: 510-643-1874
Email: ucb.digital.health@berkeley.edu

Each party may change its address and that of its representative for notice by giving notice in the manner provided above.

IN WITNESS WHEREOF, the parties hereto have duly executed this BA AGREEMENT.

The Regents of the University of California
on behalf of the University of California,
Berkeley, School of Optometry

CLINIC NAME

Signature

Signature

NAME

TITLE

Date

Date

SAMPLE