Version 1.1



# Operational Training: New IDEAS Coinsurance Reimbursement Program



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# **Study Background**

- Financial burden is a common recruitment barrier for participation in Alzheimer's and dementia research.
- For patients participating in the New IDEAS Study, the amyloid PET scan is a billable and covered procedure by Medicare.
  - However, Medicare and Medicare Advantage plans only cover a portion of the reimbursable cost that is billed.
- Prior to January 1<sup>st</sup>, 2022, if a patient did not have supplemental insurance, the patient was responsible for the remaining coinsurance amount for the amyloid PET scan.





## **Coinsurance Reimbursement Program**

Effective January 1<sup>st</sup>, 2022, the Study Sponsor will pay for the coinsurance amounts that Medicare beneficiaries participating in the study would otherwise owe for Medicare-reimbursable amyloid PET scans provided during the study, regardless of financial need.

Benefits of the Coinsurance Reimbursement Program:

Minimizes patient costs associated with the study

Ensures broad participation of patients Increases generalizability of the study findings



# **Coinsurance Reimbursement Program Overview**

Prior to January 1<sup>st</sup>, 2022:

Eligible patient **without** supplemental insurance receives amyloid PET scan. Medicare billed for scan; Patient does not have supplemental insurance to cover unpaid coinsurance.

Patient responsible for unpaid coinsurance. This cost varies by insurance, region and facility type.

#### New Coinsurance Reimbursement Program; Effective January 1<sup>st</sup>, 2022

Eligible patient **without** supplemental insurance receives amyloid PET scan. Medicare billed for scan; Patient does not have supplemental insurance to cover unpaid coinsurance. Study Sponsor responsible for reimbursing PET facilities for any unpaid coinsurance amount for Program eligible patients. Patient <u>will not</u> receive a bill.



## When Does the Program Start?

 Study participants who receive their amyloid PET scan on or after January 1<sup>st</sup>, 2022 are eligible to have their amyloid PET scan coinsurance obligations submitted to the study sponsor for reimbursement.





## What Costs are Reimbursed Under this Program?

#### Reimbursed

- Coinsurance\* amounts

   associated with the amyloid PET
   scan (including technical,
   professional or global charges).
- Fixed copayments not covered by patient's supplemental insurance.

#### **Not Reimbursed**

- Unmet beneficiary deductibles
- Coinsurance or copayments associated with dementia expert visits.

\* For the remainder of this training module, 'coinsurance' is inclusive of any coinsurance amounts and fixed copayments associated with the amyloid PET scan.



# To Which Patients Does this Program Apply?

- Not every patient enrolled in New IDEAS will require and/or be eligible for coinsurance reimbursement through this Program.
- To be eligible for coinsurance reimbursement, a patient <u>must</u>:
  - ✓ Be enrolled in the New IDEAS Study;
  - ✓ Have Medicare as their primary insurance;
  - ✓ Receive their amyloid PET scan on or after January 1<sup>st</sup>, 2022; and
  - Owe a remaining coinsurance amount for the PET scan after all insurances (primary and supplemental, if applicable) have been appropriately billed by the PET facility.
- Unpaid coinsurance will be covered by the Sponsor regardless of patient financial need.



## **Examples of Participant Scenarios: Date of PET Scan**

#### Participant 1

Status: <u>Not</u> Eligible for Reimbursement

- Enrolled in New IDEAS
- Has Medicare as primary insurance
- Scanned <u>prior to</u> Jan 1<sup>st</sup>, 2022
- Owes a coinsurance amount for the PET scan even after all insurances have been appropriately billed by the PET facility

Participant 2

Status: Eligible for Coinsurance Reimbursement

- Enrolled in New IDEAS
- Has Medicare as primary insurance
- Scanned on Jan 1st, 2022
- Owes a coinsurance amount for the PET scan even after all insurances have been appropriately billed by the PET facility

#### **Participant 3**

Status: Eligible for Coinsurance Reimbursement

- Enrolled in New IDEAS
- Has Medicare as primary insurance
- Scanned <u>after</u> Jan 1<sup>st</sup>, 2022
- Owes a coinsurance amount for the PET scan even after all insurances have been appropriately billed by the PET facility



### **Examples of Participant Scenarios: Insurance Coverage**

#### Participant 4

Status: <u>Not</u> Eligible for Reimbursement

- Enrolled in New IDEAS
- Has Medicare as primary insurance AND supplemental insurance that cover 100% of scan
- Scanned on or after Jan 1<sup>st</sup>, 2022
- Does not owe a coinsurance amount for the PET scan after all insurances billed by the PET facility

#### Participant 5

Status: Eligible for Coinsurance Reimbursement

- Enrolled in New IDEAS
- Has Medicare as primary insurance; No supplemental insurance
- Scanned on or after Jan 1<sup>st</sup>, 2022
- Owes a coinsurance amount for the PET scan even after all insurances have been appropriately billed by the PET facility

#### Participant 6

Status: Eligible for Coinsurance Reimbursement

- Enrolled in New IDEAS
- Has Medicare as primary insurance AND supplemental insurance that covers a part of the scan
- Scanned on or after Jan 1<sup>st</sup>, 2022
- Owes a coinsurance amount for the PET scan even after all insurances have been appropriately billed by the PET facility



### **Examples of Participant Scenarios: Consent Date**

#### **Participant 7**

Status: Eligible for Coinsurance Reimbursement

- Enrolled in New IDEAS and signed approved ICF without\* Coinsurance Reimbursement Program Language prior to Jan 1<sup>st</sup>, 2022
- Scanned on or after Jan 1<sup>st</sup>, 2022 and otherwise meets Program eligibility criteria

\*Advarra IRB determined at the Sponsor-level that reconsent is not necessary for patients already enrolled and active in New IDEAS. Date of consent will not affect Coinsurance Reimbursement Program eligibility.

#### **IDEAS-Study.org**

#### **Participant 8**

Status: Eligible for Coinsurance Reimbursement

- Enrolled in New IDEAS and signed approved ICF with Coinsurance Reimbursement Program Language on or after Jan 1<sup>st</sup>, 2022
- Scanned on or after Jan 1<sup>st</sup>, 2022 and otherwise meets Program eligibility criteria

#### **Participant 9**

Status: Eligible for Coinsurance Reimbursement

- Enrolled in New IDEAS and signed approved ICF without Coinsurance Reimbursement Program Language on or after Jan 1<sup>st</sup>, 2022
- Scanned on or after Jan 1<sup>st</sup>, 2022 and otherwise meets Program eligibility criteria



## **New IDEAS Coinsurance Reimbursement Policy**

- The New IDEAS Study team has instituted the following Policy, which is intended to outline the study's Coinsurance Reimbursement Program and the obligations set forth for participating PET imaging facilities and dementia practices.
- All PET imaging facilities and dementia practices that choose to participate in the New IDEAS study must adhere to this Policy.
  - Failure to comply with this policy or requirements specified by the New IDEAS Study will
    result in termination of the participating PET imaging facility or dementia practice as
    detailed in the study's executed legal agreement.
- Sites and Facilities are highly encouraged to review the list of <u>Frequently Asked</u> <u>Questions</u> compiled by the study operations team.

<u>Click Here</u> to Read the Full New IDEAS Study Coinsurance Reimbursement Program Policy



## **Coinsurance Reimbursement Program Policy Summary**

Pursuant to guidance issued by the Department of Health and Human Services Office of Inspector General (HHS OIG), the New IDEAS Coinsurance Reimbursement Program will apply the following policies:

- Reimbursement is not provided for patients who have supplemental insurance, such as Medigap, that covers 100% of any coinsurance obligations unmet by their primary insurer.
- Participating imaging facilities will receive a direct payment from the study sponsor (American College of Radiology) for coinsurance amounts related to the amyloid PET scan, that a study participant would otherwise owe.
- Allowable components of the coinsurance amounts to be reimbursed by the study include technical, professional, or global charges.
- Fixed co-payments are also permissible for reimbursement; however, the study will not provide reimbursement for any unmet beneficiary deductibles.
- Coinsurance assistance must not be part of any advertisement or solicitation relating to participation in the study. Study participants are made aware of their cost obligations during the informed consent process.



# **Coinsurance Reimbursement Program Guide for PET Facilities**



# **PET Facility Checklist:**

- Fully execute the New IDEAS Study Clinical Data and Image Access Agreement, and Addendum #1, which is required if your facility already has a signed agreement in place.
- Delegate the role of 'Facility Finance User' to an employee at your facility.
- Submit the necessary banking and tax information via the New IDEAS Study portal.
- Continue to properly bill all active insurances that the study participant has (primary and supplemental, if applicable) before submitting final coinsurance obligations to the study for reimbursement.
- Implement facility-level operational changes to ensure patients eligible for coinsurance reimbursement do not receive bills from the PET facility or professional component entity.
- Implement facility-level operational changes to ensure that co-payments or coinsurances are not collected at time of service for patients eligible for the Program.
- Submit the <u>Coinsurance Reimbursement Form</u> via the New IDEAS Study portal for each patient that has a coinsurance obligation that is not covered by his/her health insurance plan(s).
- Manage and resolve any incorrect patient billing situations (i.e. if a bill is accidentally issued to and/or paid for by a study participant).



## **PET Facility Contractual Requirements**

#### **Contract Scenario 1:**

Your PET Facility currently has a fully executed Clinical Data and Image Access Agreement with Study Sponsor.

#### To Do:

 ✓ Forward Amendment #1 Template containing Coinsurance Reimbursement
 Program Language to the appropriate legal contact within your organization.
 ✓ Fully execute Amendment #1 with the Study Sponsor.

#### **Contract Scenario 2:**

Your PET facility *does not* currently have a fully executed Clinical Data and Image Access Agreement with Study Sponsor.

#### To Do:

 ✓ Forward updated Agreement Template containing Coinsurance Reimbursement
 Program Language to the appropriate legal contact within your organization.
 ✓ Fully execute the Updated Agreement with the Study Sponsor.

Contract-specific questions or needs regarding the updated Agreement Template and/or Amendment #1 Template?

> Contact the New IDEAS Operations Team newideas@acr.org





## **Event Timeline for PET Facilities**



## **Facility User Roles in the New IDEAS Portal**

• To access your Facility's account in the New IDEAS Portal, your facility administrator needs to assign you a user role. (Note: a single user can have more than one role in the database).

	Facility Administrator	Interpreting Radiologist	Facility User	Facility Finance User
•	Automatically assigned to the person who initially submits the facility pre-registration form (next slide) Has complete administrative functionality in the New IDEAS portal Responsible for administrative duties associated with facility registration and addition of staff profile accounts Has view access to all forms and edit/submission access to all forms except Amyloid PET Assessment Form Has edit/submission access to the Coinsurance Reimbursement Form, but NOT Banking/Tax information for Facility	<ul> <li>Has view, edit and submission access to all case report forms</li> <li>Only user role that has edit and submission access to Amyloid PET Assessment Form</li> </ul>	<ul> <li>Has view access to all forms and edit/submission access to all forms except Amyloid PET Assessment Form</li> </ul>	<ul> <li>New role for Coinsurance Reimbursement Program</li> <li>Only user role that has access to facility finance portal</li> <li>Responsible for submitting facility banking and tax information</li> <li>Has edit/submission access to the Coinsurance Reimbursement Form</li> <li>Has view only access to Case Registration Form</li> </ul>
		an't accors your facilit	twic account?	

#### **IDEAS-Study.org**

Can't access your facility's account? Email newideas@acr.org



## Coinsurance Reimbursement Program Guide for PET Facilities: Step-by-Step Operations for the New IDEAS Portal



# **Step 1.** Assign a Facility Finance User to New IDEAS Portal

- a. Facility Administrators must complete the following steps:
  - 1. Login to the <u>New IDEAS portal</u>.
  - 2. Select "Facility Management" Tab.
  - 3. Select "Users" from drop-down menu or left-aligned menu.
  - 4. Select "Add New User" (Note: one individual on your team can have multiple roles, but that individual needs to be added as a user for each role they will perform in the study).
  - 5. Select "Facility Financer User" as User Type and complete profile.
- b. An automatic email will be sent to the email address associated with the user with instructions for activating the account.
  - i. Note: the link contained in the email will expire after 10 days. If the facility users link expires, instruct the user to email <u>newideas@acr.org</u>.
- c. Instruct the new Finance User to check their email account for the activation email (including junk/spam folders).



# **Step 2.** New Finance User Must Activate Access to New IDEAS Portal

#### a. Facility Finance Users: Identify the activation email containing the portal activation link

Subject: IDEAS-Study Finance User Registration Confirmation

Facility Name: <facility Name> Facility ID#: <facility ID>

Your Facility Administrator has registered you as staff for the New IDEAS Study.

\* To activate account access to the New IDEAS portal, click on the link that follows statement:

To log in to New IDEAS please access the following secure New IDEAS link and complete the steps outlined above: <CLICK SECURE LINK>

Please read the following instructions before clicking on the study link below.

## b. Login to the New IDEAS Portal via the secure link\* contained in the Automatic email you received from <a href="mailto:newideas@acr.org">newideas@acr.org</a>.

- a. New users without existing New IDEAS accounts: create and activate your account and set up multifactor authentication according to login instructions.
- b. Users with existing New IDEAS accounts: Log in with your existing email address and password.



The New IDEAS (Imaging Dementia—Evidence for Amyloid Scanning) Study is managed by the American College of Radiology and thus requires an ACR ID (username) to access the recently upgraded database.

## **Step 3.** Navigate to Your Facility's Registration Page

- a. Select your Facility ID number from the "Select a Site" drop-down menu.
  - Tip: your facility ID number is listed at the top of the activation email and starts with a "4."



Welcome to the New IDEAS Study PET Facility/Referring Physician Practice Data Center



#### Subject: IDEAS-Study Finance User Registration Confirmation

# **Step 4. Complete Banking and Tax Information for the Facility**

- a. Select "Financial Information" Tab
- b. Select "Bank and Tax Information"
- c. Select your facility's billing structure.
  - i. See example below. (Note: if you are not sure, please contact <u>newideas@acr.org</u>).

#### **Bank and Tax Information**

Please select whether or not your imaging facility requires separate bank accounts for coinsurance reimbursement of professional and technical components

- d. Enter banking and tax information for applicable accounts.
- e. Save and Submit.





# **Step 5.** View the List of Cases Eligible for **PET Scan Coinsurance Reimbursement**

- Select "Data Collection" Tab
- Select "Coinsurance Reimbursement" (Note: a patient's Coinsurance Reimbursement Form becomes available <u>after</u> the PET scan Completion form has been submitted).

Data Collection -	Facility Management -	Financial Information -	Facility payments -		
Case Registration					
Coinsurance Reimb	pursement				

 The preset filters will show you the list of cases that have both A) completed a PET scan and B) have a form ready for Reimbursement

Case Registration	➡ Filter Patient Status: Eligible × Available Form: Reimbursement ×					
Coinsurance Reimbursement						
	Case #	Stage	Status	Patient	Registration	Forms



# **Step 6. Identify a Coinsurance Reimbursement Form for an Eligible Case**

- a. Only Patients with an outstanding coinsurance balance will need a Coinsurance Reimbursement Form submitted.
- b. Identify the patient by their Case ID number or Patient Name.
- c. Complete blue Reimbursement Form for all Program-eligible patients at Stage "PET Scan Form Completed."





## **Example Coinsurance Reimbursement Form**

	New IDEAS study-specific Case ID number for patient identification and email correspondence with Study staff. Case # 50000 John Doe, 10/01/1956	Tab for Access to Coinsurance Reimbursement Form
	Case Registration	Reimbursement
Case Registration		
Coinsurance Reimbursement	The form was approved.	
Submit Data Change	Coinsurance Reimbursement Form	
Data Change Request button to be used for any changes to the form <u>after</u> submission.	Instructions: Ensure that all the following items have been completed reimburse the coinsurance that the study participant otherwise would Explanation of Benefits (EOB). Allowable components of the coinsura payments are also considered reimbursable charges under this progr form should not be completed by an industry representative and show obtained. Send any questions, comments, or special circumstances t	I prior to submitting a request for reimbursement. The study sponsor will only I owe for the amyloid PET scan used in the study, as documented by the Medicare ance amounts include technical, professional, or global charges. Fixed co- ram. Sponsor will not reimburse for charges related to the patient's deductible. This uld only be submitted once all applicable insurers have been billed and EOBs to the New IDEAS Study Team at NewIdeas@acr.org.



#### **IDEAS-Study.org**

## **Step 7. Complete the Coinsurance Reimbursement Form**

Questions about this Form? Email newideas@acr.org

## To accurately complete the Coinsurance Reimbursement Form, the Financer User or Facility Administrator will need to:

- 1. Verify patient's general information and confirm pre-populated fields:
  - PET facility provider type (Hospital-based/Not hospital-based)
  - Patient's Medicare type (Traditional/Medicare Advantage Plan)
  - Supplemental insurance (Yes/No)
  - Scan Date
  - Radiopharmaceutical administered
- 2. Upload required documentation for reimbursement
  - Upload patient's Explanation of Benefits (EOB) documents for all insurances
  - PDF document only; max file size 10Mb)
  - Multiple documents can be uploaded
  - Multiple documents <u>must be</u> uploaded before submission if technical and professional components are billed separately. Requests for partial payments will not be accepted.
- 3. Provide an attestation of coverage
  - Confirm that ALL insurances have been billed appropriately and all appeals have been pursued and resolved with Medicare and any supplemental insurer.
- 4. Indicate the total amounts requested for reimbursement
  - Entered amounts must match the coinsurance amounts shown on provided EOBs.



# **Step 8.** Review Completed Cases and Payment Report

- a. After a Coinsurance Reimbursement Form is submitted, the form will follow the Coinsurance Reimbursement Form approval process.
- b. ACR remits payment for approved submissions on a monthly basis.



# **Step 9.** View List of Approved Forms and Paid Reimbursement Amounts

- a. The New IDEAS database will update after monthly reimbursement payments to PET facilities.
- b. Select "Facility Payments Tab"
- c. Select "Facility Payment Report"
- d. Use Filter to Search for Case ID or by Date

#### **Facility Payment Report**

Facility Payment Report	+ Filter				
Note: Payment Type separated for each Case # if Facility does not bill globally.	Case # 50000 50000	Payment Type Professional/global Technical	Date Received           11-Nov-2021           11-Nov-2021	Amount 10.00 20.00	Transaction Date 11-Nov-2021 11-Nov-2021



# How to Make a Change to a Submitted Coinsurance Reimbursement Form

- 1. Login to the <u>New IDEAS Portal</u>
- 2. Select "Coinsurance Reimbursement"
- 3. Click on the Case # of interest.
- 4. Select the Coinsurance Tab.
- 5. Select "Submit Data Change."
- 6. Detail your requested data changes in the comment box.
- Click "Send." A notification will be sent to ACR New IDEAS data management staff for review.



Site #: 6988 Case #: 50011 Form: Socio-Demographics User: Practice Admin (00uup0wtph95juouK0h7) Detail your requested data change(s) below. You will be contacted if clarification of request is needed:		
Case #: 50011 Form: Socio-Demographics User: Practice Admin (00uup0wtph95juouK0h7) Detail your requested data change(s) below. You will be contacted if clarification of equest is needed:	Site #:	6988
Form: Socio-Demographics User: Practice Admin (00uup0wtph95juouK0h7) Detail your requested data change(s) below. You will be contacted if clarification of equest is needed:	Case #:	50011
User: Practice Admin (00uup0wtph95juouK0h7) Detail your requested data change(s) below. You will be contacted if clarification of request is needed:	Form:	Socio-Demographics
Detail your requested data change(s) below. You will be contacted if clarification of request is needed:	User:	Practice Admin (00uup0wtph95juouK0h7)
	Detail your re request is ner	quested data change(s) below. You will be contacted if clarification of you eded:

Please submit your requested data change for this form



Close

## **Real-World Submission Tips**

### **BEFORE** submitting the Coinsurance Reimbursement Form:

- ✓ Review Medicare Type checked on question 1b and confirm it matches EOB for upload.
- ✓ Review Supplemental Insurance response to question 1c.
  - If 1c indicates the patient has supplemental insurance and/or the EOB shows a balance was forwarded to a supplemental insurance, ACR staff requires EOB documentation of supplemental insurance including applicable appeal/denial documentation.
- ✓ When completing question 4:
  - If facility bills GLOBALLY, all requests should be placed in line 4a.
  - Sum of 4a and 4b must match total coinsurance indicated on EOB(s).
  - Subtract patient <u>deductible</u> from outstanding balance, if applicable.
- ✓ Confirm that requests for reimbursement amounts that were denied by insurance are accompanied by supporting EOB, appeal and denial letter documentation.
- ✓ Redact EOB of any PII for **non**-New IDEAS patients.



## **Real-World Submission Example**



# **Coinsurance Reimbursement Program Guide for Dementia Practices**



## **Dementia Practice Checklist**

- 1. Download your 1) site-level amendment approval letter and 2) approved informed consent form from <u>Advarra IRB</u> that contains coinsurance reimbursement language.
- Practice Administrators or Regulatory Users need to upload 1) site-level approval letter and
   approved ICF document to the <u>New IDEAS portal</u> under section IRB approval documents.
- 3. Consent all prospective study participants on the most recently approved version of the ICF document downloaded in Step 1.
  - Per the IRB of record's determination, currently enrolled study participants do not need to be reconsented with the updated and IRB approved ICF.
- 4. Inform site team members that coinsurance assistance <u>must not</u> be part of any advertisement or solicitation relating to participation in the study.
  - Study participants are made aware of their cost obligations during the informed consent process.



## Where Can I Find a Copy of My Site's New Informed Consent Form and Approval Letter?

- Log into <u>www.CIRBI.net</u> with your CIRBI username and password.
- Select the "New IDEAS Study" from your dashboard.
- 3. Select Tab "IRB Issued Documents."
- 4. Download and save your documents to your computer.
- After download, Practice administrators need to upload your site-level documents to the <u>New</u> <u>IDEAS Portal.</u>

**IDEAS-Study.org** 

rrent State	American College o	of Radiology	- (Pro00046342 - Mult	i-Site Protocol )			
Approved	Protocol Title:	New IDEAS: Imaging Dementia—Evidence for Amyloid Scanning Study					
View Protocol Application		A Study to Impr	ove Precision in Amyloid	PET Coverage and Pa	tient Care		
Printer Version	Expiry/Expiration Date:	9/17/2021					
The Polar	Review Interval:	12 Month					
View Differences	Related Protocol (if applicable):						
Activities	Company:	Advarra IRB					
Contact IRB	RB Advarra Client Services Pathol Aubaces (000 7/15 membra EST) (512 979 2113 ( Pathol Aubaces Optimum com)					a) (a	
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omission Forms	IRB Issued Documents	Htory	Attachments	Clarifications	Site Information	Modifica	
Modification							
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SAE/UADE Report	IRB Issued Documents				formed Conse	nt Form	
Deviation/Violation Report					ionned conse		
Auda Banad	Informed Consent Documer	nts:					
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UAP Report	Master Main ICF Pro00	046342 Sep2920.	docx(0.02)				
Non-Compliance Report						- T	

Questions about Regulatory documents? Email newideas-regulatory@acr.org



# Informed Consent Guidance: Will Patients Endure Any Costs?

- **Best Practice**: Determine and discuss any potential out-of-pocket costs with the patient/family as part of the shared decision making prior to ordering the scan.
- As a New IDEAS Study participant, the amyloid PET scan is a covered procedure by Medicare.
- Patients may be responsible for:
  - Unmet beneficiary deductibles
  - Coinsurance or copayments associated with dementia expert visits
  - Coinsurance or copayments associated with the amyloid PET scan (if scanned prior to January 1<sup>st</sup>, 2022).
- Patients who received a scan on or after January 1<sup>st</sup>, 2022 are <u>not</u> responsible for:
  - Coinsurance amounts associated with the amyloid PET scan (including fixed copayments and technical, professional or global charges) not covered by patient's supplemental insurance.



## **Common Questions and Answers**

- The New IDEAS Operations Team strongly encourages all site and facility staff members to download and review the following resources:
  - Program-specific Frequently Asked Questions Sheet
  - Program Policy
  - Updated Case Report Form Packets
    - Dementia Practice Case Report Form Packet
    - PET Facility Case Report Form Packet
- Additional study resources can be found on the <u>New IDEAS Study</u> <u>Website</u>.



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## **Questions**?

### **Contact the New IDEAS Operations Team**

### newideas@acr.org

### 215-574-3150 ext. 4156



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