September 8, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
US Department of Health & Human Services
200 Independence Avenue SW
Washington, DC 20543

Re: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction

Dear Administrator Brooks-LaSure,

On behalf of the American College of Gastroenterology (ACG), American Gastroenterological Association (AGA) and the American Society for Gastrointestinal Endoscopy (ASGE), we appreciate the opportunity to provide comments on the CY 2024 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems proposed rule (CMS-1786-P). Together, our societies represent virtually all practicing gastroenterologists in the United States. We thank the Centers for Medicare & Medicaid Services (CMS) for its ongoing effort to engage with stakeholders to better understand the evolving healthcare environment and believe that the PFS comment solicitation on these issues is a positive step in this ongoing dialogue.

There are several provisions in the proposed rule impacting practicing gastroenterologists and Medicare beneficiaries. In this letter, we offer comments on the following provisions:

- Movement of CPT codes 43252, 43263, 43275, 44384 from APC 5303 to APC 5302
- CPT Code 43497 - 2 Times Rule Violation
- EchoTip
- Proposed Modification of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure Denominator Change to Align with Current Clinical Guidelines Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination
- Alimetry New Technology APC
- List of Covered Procedures in the ASC Setting
Movement of CPT codes 43252, 43263, 43275, 44384 from APC 5303 to APC 5302

For 2024, CMS is proposing to move CPT codes 43252, 43263, 43275, 44384 from Ambulatory Payment Classification (APC) 5303 (Level 3 Upper GI Procedures) to APC 5302 (Level 2 Upper GI Procedures):

- 43252 Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy
- 43263 Endoscopic retrograde cholangiopancreatography (ERCP); with pressure measurement of sphincter of Oddi
- 43275 Endoscopic retrograde cholangiopancreatography (ERCP); with removal of foreign body(s) or stent(s) from biliary/pancreatic duct(s)
- 44384 Ileoscopy, through stoma; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)

The proposed APC reassignment of the above codes from APC 5303 to APC 5302 results in a payment rate decrease of 44 percent for CPT codes 43252, 43263, 43275, 44384. CMS does not discuss the rationale for the proposed APC reassignment in the proposed rule, so we are unable to respond to any concerns the Agency had that led to this decision.

Proposed Reassignment for CPT codes 43252, 43263, 43275, 44384 from APC 5303 to APC 5302

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<tr>
<th>HCPCS Code</th>
<th>CY 2023 APC</th>
<th>CY 2023 Relative Weight</th>
<th>CY 2023 Payment Rate</th>
<th>CY 2024 APC</th>
<th>CY 2024 Relative Weight</th>
<th>CY 2024 Payment Rate</th>
<th>% Change, Relative Weight</th>
<th>% Change, Payment Rate</th>
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</thead>
<tbody>
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<td>5303</td>
<td>38.0989</td>
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<td>5302</td>
<td>20.9526</td>
<td>$1,833.10</td>
<td>-45%</td>
<td>-44%</td>
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<tr>
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<td>5303</td>
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<td>$3,260.69</td>
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<td>20.9526</td>
<td>$1,833.10</td>
<td>-45%</td>
<td>-44%</td>
</tr>
<tr>
<td>43275</td>
<td>5303</td>
<td>38.0989</td>
<td>$3,260.69</td>
<td>5302</td>
<td>20.9526</td>
<td>$1,833.10</td>
<td>-45%</td>
<td>-44%</td>
</tr>
<tr>
<td>44384</td>
<td>5303</td>
<td>38.0989</td>
<td>$3,260.69</td>
<td>5302</td>
<td>20.9526</td>
<td>$1,833.10</td>
<td>-45%</td>
<td>-44%</td>
</tr>
</tbody>
</table>

Our societies strongly urge CMS not to finalize the proposed reassignment of CPT codes 43252, 43263, 43275, 44384 from APC 5303 to APC 5302, which would result in a payment decrease of approximately 44 percent. We further recommend that CMS publish the rationale for all future proposed APC reassignments in the text of the proposed rule to provide the public adequate time to assess the proposed changes and submit comments to CMS, where appropriate.

CPT Code 43497 - 2 Times Rule Violation

As per Section 1833(t)(2) of the Social Security Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group. This is also referred to as the “2 times rule.”
We believe the proposed CY 2024 OPPS cost statistics file demonstrates a 2 times rule violation in APC 5303 (Level 3 Upper GI Procedures). **We ask CMS to review this potential violation of the 2 times rule and correct it by placing CPT code 43497 (Lower esophageal myotomy, transoral (i.e., Peroral Endoscopic Myotomy [POEM]) into APC 5331 (Complex GI Procedures).**

There were 661 single claim Medicare outpatient procedures reported for CPT code 43497 in 2022. This volume represents 3% of the volume in the currently assigned APC 5303. Therefore, CPT code 43497 meets the significant volume requirement.

The geometric mean cost reported for CPT code 43497 is $6,735.75 and is more than twice the geometric mean for the least costly CPT code in APC 5303 43260 with a geometric mean cost of $3,226.97. In addition, the geometric mean cost of CPT code 43497 is higher than the geometric mean cost of APC 5331 ($6,736 vs. $5,518) and is greater than the three lowest cost significant procedures assigned to APC 5331.

*Given the 2 times rule violation and the geometric mean cost of CPT code 43497 relative to other procedures assigned to APC 5303, we recommend CMS assign CPT code 43497 to APC 5331 with a proposed payment of $5,455.74 in CY 2024.* Clinically, CPT code 43497 is aligned with all other complex gastroenterology procedures in APC 5331. Economically, the median costs associated with CPT code 43497 more closely align with the payment for APC 5331. **We, therefore, ask CMS to finalize placement of CPT code 43497 into APC 5331 in the FY 2024 final rule.**

**EchoTip Insight Portosystemic Pressure Gradient Measurement System Transitional Pass-Through Payment**

For 2024, CMS has posed several questions regarding whether EchoTip Insight Portosystemic Pressure Gradient Measurement System (EchoTip) meets criteria for inclusion in the Transitional Pass-Through Payment. EchoTip is used in the diagnosis and management of patient populations with chronic liver diseases (CLDs), and especially with non-alcoholic fatty liver Disease (NAFLD). The EchoTip device directly measures pressures in the hepatic and portal venous vasculatures and is used in conjunction with an ultrasound endoscope. The physician measures the portosystemic pressure gradient via endoscopic ultrasound guidance, via a single-use, disposable device consisting of the EchoTip Insight Needle, a connecting tube, and a Compass CT transducer. EchoTip is also supplied with a 10 ml syringe.

Our societies believe the criteria for newness, clinical improvement and cost have been met based on the information provided. The FDA approval for this device was obtained June 2022 which is within the required 3 years. The device is integral to the service provided, is used for one patient only, comes in contact with human skin, and is applied in or on a wound or other skin lesion. Both the hepatic vein and portal vein are punctured through the liver parenchyma to obtain pressure measurements. There are currently no other devices available in the marketplace nor previous device categories which may have encompassed the EchoTip device. Finally, EchoTip provides substantial clinical improvement over current standards of care by providing a new approach to diagnosis and management of patients with CLDs, allowing pressure measurements regardless of disease state and the ability to simultaneously acquire several critical pieces of clinical information through pressure measurement and liver biopsy.
We encourage CMS to establish a new device category for transitional pass-through payment status for the EchoTip.

Proposed Modification of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure Denominator Change to Align with Current Clinical Guidelines Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination

In May 2021, the United States Preventive Services Task Force (USPSTF) issued a revised Final Recommendation Statement on CRC Screening. The USPSTF recommended that adults who do not have signs or symptoms of CRC and who are at average risk for CRC begin screening at age 45 instead of the previous recommendation of age 50. In addition, multiple professional organizations, including the ACS, American Society of Colon and Rectal Surgeons, and the U.S. Multi-Society Task Force on Colorectal Cancer (which represents the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy), recommend that people of average risk of CRC start regular screening at age 45.

Based on the recent changes in clinical guidelines to begin CRC screening at age 45 instead of age 50, CMS proposes to modify the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (the Colonoscopy Follow-Up Interval) measure to align with updated clinical guidelines beginning with the CY 2024 reporting period/CY 2026 payment determination. Specifically, CMS proposes to modify the measure denominator’s language to “all patients aged 45 to 75 years” for the Hospital OQR Program as opposed to “50 to 75 years”. This aligns with changes finalized in the CY 2023 PFS final rule where CMS adopted the modified Colonoscopy Follow-Up Interval measure for the Merit-based Incentive Payment System (MIPS) and expanded the regulatory definition of “colorectal cancer screening tests” and waive cost sharing for a necessary follow-on screening colonoscopy after a Medicare covered noninvasive stool-based colorectal cancer (CRC) screening test returns a positive result and for permitting coverage of certain CRC screening tests beginning at age 45.

Our societies thank CMS for proposing this modification which will align the minimum age requirement for CRC screening across quality reporting programs and recent changes in clinical guidelines which recommend that adults who do not have signs or symptoms of CRC and who are at average risk for CRC begin screening at age 45 instead of age 50.

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**Alimetry New Technology APC**

In the Hospital Outpatient Prospective Payment System July 2023 Update, Transmittal number R12077CP, CMS announced the creation of new HCPCS code C9787 *(High-resolution Gastric Electrophysiology Mapping Procedure (GEMS))* to describe GEMS patient symptom profiling. HCPCS code C9787 was assigned to APC 5723 *(Level 3 Diagnostic Tests and Related Services)*. However, with a payment of $512.71, APC does not adequately cover the resource costs associated with the GEMS system.

Based on information supported by invoices included in Attachment A, the cost of the array alone is $990, and the supplies are $499. The necessary system, including dock, reader and computer system, is $10,000. Additionally, staff time to administer the procedure and monitor the patient and a room with reclining chair are necessary. We understand that the expected total cost to the facility is $1,800.

With the expected cost of the device at $1,800 and the payment for APC 5723 at $512.71, it is unlikely that any facilities will allow Medicare beneficiaries to access this procedure. We understand that CMS requires sufficient data claims to validate the assigned APC; however, with such a disparity between costs and payment, it is unlikely that CMS will receive enough claims for this assessment.

*We strongly urge CMS to remove C9787 from APC 5723 and assign it to an APC that is more closely aligned with the costs as represented by the invoices provided.*

**List of Covered Procedures in the ASC Setting**

As in our societies’ previous comment letters on the 2018, 2019 and 2020 HOPPS/ASC proposed rules, we continue to urge CMS to expand the list of covered procedures in the ASC that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. In our letters, we argued that several gastrointestinal (GI) diagnostic tests within the medicine range of CPT codes (90000 to 99999) for which separate payment is allowed under the OPPS should be added as ASC covered ancillary services. We noted that CPT code 91035, *(Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation)*, has been a covered procedure in the ASC setting since CY 2015. However, other similar GI diagnostic tests which are also safely performed in the ASC are not covered in the ASC setting, which is lower cost than the hospital outpatient setting.

The following 15 diagnostic tests in Table 1 below fall within the medicine range of CPT codes (90000 to 99999) for which separate payment is allowed under the OPPS are ASC covered ancillary services and are safely performed in the ASC setting.
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<th>CPT Code</th>
<th>Long Descriptor</th>
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<tr>
<td>91010</td>
<td>Esophageal motility (manometric study of the esophagus and/or gastroesophageal junction) study with interpretation and report;</td>
</tr>
<tr>
<td>91013</td>
<td>Esophageal motility (manometric study of the esophagus and/or gastroesophageal junction) study with interpretation and report; with stimulation or perfusion (eg, stimulant, acid or alkali perfusion) (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>91020</td>
<td>Gastric motility (manometric) studies</td>
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<tr>
<td>91022</td>
<td>Duodenal motility (manometric) study</td>
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<td>91030</td>
<td>Esophagus, acid perfusion (Bernstein) test for esophagitis</td>
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<td>91034</td>
<td>Esophagus, gastroesophageal reflux test; with nasal catheter pH electrode(s) placement, recording, analysis and interpretation</td>
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<tr>
<td>91037</td>
<td>Esophageal function test, gastroesophageal reflux test with nasal catheter intraluminal impedance electrode(s) placement, recording, analysis and interpretation;</td>
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<tr>
<td>91038</td>
<td>Esophageal function test, gastroesophageal reflux test with nasal catheter intraluminal impedance electrode(s) placement, recording, analysis and interpretation; prolonged (greater than 1 hour, up to 24 hours)</td>
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<tr>
<td>91040</td>
<td>Esophageal balloon distension study, diagnostic, with provocation when performed</td>
</tr>
<tr>
<td>91110</td>
<td>Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with interpretation and report</td>
</tr>
<tr>
<td>91111</td>
<td>Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus with interpretation and report</td>
</tr>
<tr>
<td>91112</td>
<td>Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report</td>
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<tr>
<td>91117</td>
<td>Colon motility (manometric) study, minimum 6 hours continuous recording (including provocation tests, eg, meal, intracolonic balloon distension, pharmacologic agents, if performed), with interpretation and report</td>
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<tr>
<td>91120</td>
<td>Rectal sensation, tone, and compliance test (ie, response to graded balloon distention)</td>
</tr>
<tr>
<td>91122</td>
<td>Anorectal manometry</td>
</tr>
</tbody>
</table>
Specifically, we would like to call CMS’ attention to CPT code 91040 in comparison to CPT code 91035, which has been a covered procedure in the ASC setting since 2015. When adding CPT code 91035 to the ASC covered list, CMS’ supporting rationale for the decision was that CPT code 91035 is integral to an ASC covered procedure. However, CPT code 91035 was billed alone 70.9 percent of the time according to 2021 Medicare claims data. The top ASC covered surgical procedure that CPT code 91035 was billed together with in 2021 was CPT code 43239 at 17.7 percent of the time and CPT code 43235 at 5.1 percent. In comparison, CPT code 91040 was billed alone only 10% of the time. The top procedures that CPT code 91040 was billed together with were CPT codes 43239, 43235 and 43499, which are all ASC covered surgical procedures. Collectively, CPT code 91040 was billed with one of those three CPT codes 75.7 percent of the time. Therefore, if CPT code 91035 meets CMS’ threshold for the criteria “integral to an ASC covered procedure,” then CPT code 91040 must also meet that threshold because it is billed together with an ASC covered procedure far more frequently than CPT code 91035.

We ask CMS to add all the CPT codes in Table 1 to the list of ASC covered procedures because they are all safely performed in the ASC setting and doing so will lower costs to CMS since the ASC setting is lower cost than the hospital outpatient department. Additionally, we ask CMS to specifically add 91040 because it is integral to an ASC covered procedure, especially when compared to 91035 which CMS added to the list of covered ASC procedures in 2015.

Conclusion

Thank you for the opportunity to comment on the CY 2024 PFS proposed rule and issues concerning gastroenterology. Our societies:

- Urge CMS not to finalize the proposed reassignment of CPT codes 43252, 43263, 43275, 44384 from APC 5303 to APC 5302.
- Recommend that CMS publish the rationale for all future proposed APC reassignments in the text of the proposed rule to provide the public adequate time to assess the proposed changes and submit comments to CMS.
- Ask CMS to correct the violation of the 2 times rule caused by assignment of CPT code 43497 (Lower esophageal myotomy, transoral (i.e., Peroral Endoscopic Myotomy [POEM]) to APC 5303 (Level 3 Upper GI Procedures) by placing CPT code 43497 into APC 5331 (Complex GI Procedures).
- Encourage CMS to establish a new device category for transitional pass-through payment status for the EchoTip.
- Urge CMS to remove C9787 from APC 5723 and assign it to an APC that is more closely aligned with the costs as represented by the invoices provided.
- Ask CMS to add all the codes in Table 1 to the list of ASC covered procedures because they are all safely performed in the ASC setting and doing so will lower costs to CMS since the ASC setting is lower cost than the hospital outpatient department.
- Ask CMS to add 91040 to the list of ASC covered procedures because it is integral to an ASC covered procedure, especially when compared to 91035.

We appreciate the ongoing dialogue concerning these important issues, as well as CMS’ significant effort in the proposed rule. If you have any questions about our request or if we may provide any additional information, please contact Brad Conway, ACG, at 301-263-9000 or bconway@gi.org; Leslie Narramore,
Sincerely,

Daniel J. Pambianco, MD, FACG
President, American College of Gastroenterology

Barbara H. Jung, MD, AGAF
President, American Gastroenterological Association

Jennifer A. Christie, MD, FASGE
President, American Society for Gastrointestinal Endoscopy
### INVOICE

**BOSTON MA 02116 UNITED STATES**

<table>
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<tr>
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**Due Date: Aug 3, 2023**

Kindly Remit funds to: Commercial Checking only
Account Beneficiary Name – Alimetry Inc.
Account Number –
Routing Number –

**Subtotal**

**TOTAL USD**

### PAYMENT ADVICE

**To:** Alimetry Inc  
400 S 4th St  
MINNEAPOLIS MN 55415  
USA

**Customer**

**Account Number**

**Invoice Number**

**Amount Due**

**Due Date** Aug 3, 2023

**Amount Enclosed**

Enter the amount you are paying above
INVOICE

PHILADELPHIA PENNSYLVANIA 19104
UNITED STATES

Invoice Date: Feb 17, 2023
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Reference: [Redacted]

Alimetry Inc
400 S 4th St
MINNEAPOLIS MN 55415
USA

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400 S 4th St
MINNEAPOLIS MN 55415
USA

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Registered Office: 400 S 4th St, Minneapolis, MN, 55415, USA.
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BOSTON MA 02115
UNITED STATES

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**Invoice Date**
Nov 28, 2022

**Invoice Number**

**Reference**

**Alimetry Inc**
400 S 4th St
MINNEAPOLIS MN 55415
USA

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Account Number: [Redacted]
Routing Number: [Redacted]

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To: Alimetry Inc
400 S 4th St
MINNEAPOLIS MN 55415
USA

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Registered Office: 400 S 4th St, Minneapolis, MN, 55415, USA.
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**Subtotal**  

**TOTAL USD**  

**Due Date:** Dec 25, 2022

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## PAYMENT ADVICE

**To:** Alimetry Inc  
400 S 4th St  
MINNEAPOLIS MN 55415  
USA

**Customer**  
**Invoice Number**  
**Amount Due**  
**Due Date**  
**Amount Enclosed**

Enter the amount you are paying above

Registered Office: 400 S 4th St, Minneapolis, MN, 55415, USA.
INVOICE

BOSTON MA 02115
UNITED STATES

Invoice Date
Nov 28, 2022

Invoice Number

Reference

Description          Quantity  Unit Price  Tax       Amount USD

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Subtotal            4,990.00

TOTAL USD            4,990.00

Due Date: Dec 25, 2022

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Account Number: [redacted]
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PAYMENT ADVICE

To: Alimetry Inc
400 S 4th St
MINNEAPOLIS MN 55415
USA

Customer
Invoice Number

Amount Due  4,990.00
Due Date    Dec 25, 2022
Amount Enclosed

Enter the amount you are paying above

Registered Office: 400 S 4th St, Minneapolis, MN, 55415, USA.
# INVOICE

![Invoice Image]

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**TOTAL USD** | | | | 4,950.00

Less Amount Paid | | | | 4,950.00

**AMOUNT DUE USD** | | | | 0.00

**Due Date:** Mar 15, 2023

Kindly Remit funds to: Commercial Checking only
Account Name: Alimetry Inc.
Account Number: [Redacted]
Routing Number: [Redacted]

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# PAYMENT ADVICE

![Payment Advice Image]

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Los Angeles, CA 90048  
United States  

**Vendor:**  
Alimetry Inc  
400 S 4th St  
Minneapolis MN 55415  
USA

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<th>Tax</th>
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**Due Date:** Sep 30, 2022

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## PAYMENT ADVICE

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400 S 4th St  
Minneapolis MN 55415  
USA

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**Amount Due:** **8,482.01**  
**Due Date:** Sep 30, 2022  
**Amount Enclosed:** Enter the amount you are paying above

Registered Office: 400 S 4th St, Minneapolis, MN, 55415, USA.
### INVOICE

**Alimetry Inc**  
400 S 4th St  
MINNEAPOLIS MN 55415  
USA

**INVOICE**  
STANFORD CA 94305

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<thead>
<tr>
<th>Description</th>
<th>Quantity</th>
<th>Unit Price</th>
<th>Tax</th>
<th>Amount USD</th>
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<tr>
<td>Alimetry iPad Mini (8th Gen)</td>
<td>1.00</td>
<td>700.00</td>
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<td>Alimetry Reader</td>
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<td>4,990.00</td>
<td>Tax Exempt</td>
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<tr>
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<td>Set-Up Charge</td>
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**Subtotal**  
19,330.00

**TOTAL USD**  
19,330.00

**Due Date:** May 30, 2023

Kindly Remit funds to: Commercial Checking only

Account Beneficiary Name – Alimetry Inc.

Account Number: [Redacted]

Routing Number: [Redacted]

EIN: [Redacted]

Registered Office: 400 S 4th St, Minneapolis, MN, 55415, USA.
PAYMENT ADVICE

To: Alimetry Inc
400 S 4th St
MINNEAPOLIS MN 55415
USA

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<td>Invoice Number</td>
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<tr>
<td>Due Date</td>
<td>May 30, 2023</td>
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<td>Amount Enclosed</td>
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Enter the amount you are paying above

Registered Office: 400 S 4th St, Minneapolis, MN, 55415, USA.
INVOICE

LOS ANGELES, CA 90045
UNITED STATES

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<td>Allmetry Array-5 Pack</td>
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<td>Subtotal</td>
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<td>TOTAL USD</td>
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Due Date: Oct 23, 2022

Rewire to:
Account Beneficiary Name – Allmetry Inc.
Account Number - [Redacted]
Routing Number - [Redacted]

PAYMENT ADVICE

To: Allmetry Inc
400 S 4th St
MINNEAPOLIS MN 55415
USA

<table>
<thead>
<tr>
<th>Customer</th>
<th>Invoice Number</th>
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<table>
<thead>
<tr>
<th>Amount Due</th>
<th>Due Date</th>
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<td>Oct 23, 2022</td>
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</tbody>
</table>

Amount Enclosed

Enter the amount you are paying above

Registered Office: 400 S 4th St, Minneapolis, MN, 55415, USA.