Request for Proposal for Medical Device Alliance Reimbursement Analysis (RFP #2020-0004)

SCRA
SOUTH CAROLINA MEDICAL DEVICE ALLIANCE

I. Background

Chartered as a 501(c)3 by the state of South Carolina in 1983, South Carolina Research Authority (SCRA) is a public, non-profit corporation that fuels South Carolina's innovation economy.

The South Carolina Medical Device Alliance (MDA) is transforming how the state is inventing, advancing and commercializing medical devices to address unmet clinical needs. This multi-stakeholder partnership is the foundation of a regional innovation cluster to grow the economic impact through job creation and startup formation, as well as to attract international businesses. The MDA will advance technologies to market with multidisciplinary teams and launch startups that have been rigorously evaluated by seasoned industry experts.

Having evaluated and selected the most promising early-stage technologies, the current phase of the MDA process involves building project profiles to address aspects of medical device development that are key to commercialization. Profiles may include a regulatory assessment, reimbursement strategy, commercial/market assessment, design for manufacturability evaluation, and patent landscape analysis. Please view our other RFPs if you are interested in submitting a bid proposal for other components of the project profiles.

The project profiles will be compiled and provided to the innovator and their affiliated institution(s). The primary audience for the project profiles, however, is the Medical Device Commercialization Advisory Panel (MDCAP). The MDCAP was formed by SCRA to provide industry insight to academic innovators and technology transfer offices, prioritize technologies to advance through the MDA, and recommend the next commercially relevant steps in development. The MDCAP consists of seasoned medical device executives across disciplines, including regulatory affairs, R&D, product development, manufacturing, reimbursement and funding.

This work is supported by the Economic Development Administration's Regional Innovation Strategies i6 program, SCRA, Clemson University, and Medical University of South Carolina.

II. Scope of Solicitation

SCRA is soliciting fixed price bids for professional consulting services to develop reimbursement landscape analysis and initial reimbursement assessment reports for up to nine early-stage medical devices. Please refer to the chart below and address your experience in each of these specialties.

Technology	Specialty
External Device for Postoperative Ileus	GI
Annulus Fibrosis Repair Patch	Neurosurgery/Ortho
Surgical Guides for Dental Implants	Dental
Device to Guide PD Medication Titration	Neurology
Pediatric Concussion Assessment Device	Neurology
Localized High Frequency Stimulation (LHFS) for Myocardial Infarction Remodeling	Cardiology
Wound Dressing	Multiple
Minimally Invasive Subdural Evacuation System	Neurosurgery

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The reimbursement analysis for each technology should address the following components:

- Literature Assessment & Availability (i.e. is this technology a "me too" or radically different breakthrough than any other technology available): What is currently being reimbursed by both CMS and Private Insurers for a similar product and would the invention be able to utilize existing codes by claiming similar performance and indications for use ("me-too")? Is it covered under a current CPT or HCPCS code?
- What type of clinical data and technology assessment analysis will be needed to secure "me-too" use of another's code or to appeal for reimbursement for a new code?
- Are there any existing insurers' (including CMS) technology assessment policies that have evaluated and recommended coverage? Are there any guidelines/criteria in place regarding use? Are there any technology assessment policies that the invention is similar too that has been considered experimental/investigative by any public or private insurer?
- Is payment/reimbursement available for current or similar products and procedures, from which insurers and in what settings? Does it differ based on setting of care (ambulatory vs inpatient vs home care vs telemedicine) and insurer type? Differentiate payments for product, received by the manufacturer, from those fees received by the hospital. Identify when payments are only made globally, from which the manufacturer will have to extract payment from the provider and approximate the amounts for each.
- Examine the pros and cons of applying for any "new technology" or "transitional pass thru (TPT)" payment status in relation to the invention or highlight the historical experience and value brought, if any, for a similar technology
- Overall, how important or relevant is securing reimbursement for the invention? Can the invention displace a more expensive current alternative and use its existing code? If so, how would one go about appealing for that? Could the invention be viable for private patient payment?

All final work product will be presented in the form of a Microsoft Word document and, if appropriate, Microsoft Excel spreadsheet. In addition to the final report, the service provider will be required to virtually participate in a technology review session in July to summarize their findings for the MDCAP and answer questions from the panel.

For questions regarding the scope of work, please contact academicinnovations@scra.org.

III. Bidding and Delivery Timeline

Bid proposals are due by 5:00 PM on Wednesday, May 20th, 2020. The winning proposals will be notified on Wednesday, May 27th. The due date for the final work product is dependent on other analyses but is expected to fall in late-June. Submit all bid proposals to academicinnovations@scra.org. No proposals will be accepted by mail or hand delivery.

IV. Bid Package

Bid proposals must include a sample report, redacted as needed to protect confidentiality, that will be emulated by the service provider for the reports to be provided to SCRA. Please refer to the chart in Section II and address your experience in each of these specialties. Service provider must have expertise in the specialty areas for which they are submitting proposals. Bids do not need to encompass all eight technologies. Bids may outline work, in addition to the scope of work in Section I, which the service provider views as crucial to execution of the project. Proposals must specify the cost per report to be completed in the time frame outlined in section III – Bidding and Delivery Timeline.

Service providers may submit bid proposals for multiple SCRA RFPs. Please submit a bid under each RFP separately, but indicate if there will be pricing discounts available if selected to provide services under more than one RFP.

Due to the U.S. federal funding associated with this project, all work must be completed by U.S.-based personnel from U.S.-based entities. Please explicitly state in the bid package if the company and personnel meet these criteria.

V. Contract Terms and Conditions

The service provider must agree to a non-disclosure/confidentiality provision. Any resultant contract will include all clauses that are required under the Economic Development Administration's Regional Innovation Strategies i6 program, all clauses required by law on the date of contract execution, other mutually agreeable clauses, provisions, and terms and conditions.

This is a solicitation and does not commit SCRA to pay any cost incurred in the preparation and submission of any offer in any form or to produce or subcontract for said work. Any resultant agreement between SCRA will be subject to the provisions and Terms and Conditions of the Solicitation as well as SCRA's Standard Terms and Conditions. If you have any questions of a contractual nature, please feel free to contact sheila.riley@scra.org.