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Connecting Constituents with Federal Assistance for Health and Medical Businesses

Federal assistance for health- and medical-related groups primarily focuses on nonprofit organizations. For-profit health and medical businesses do not qualify for many of these opportunities. However, these businesses may qualify for other business-related federal assistance. Health and medical businesses include medical equipment companies, digital health companies, for-profit health care facilities, and medical device and pharmaceutical manufacturers, among others.

Federal agencies assist businesses through a number of credit and technical assistance programs. With few exceptions, the federal government typically does not award grants for starting or expanding for-profit businesses. Exceptions include certain federal grants that may be available for businesses involved in research and development (R&D) activities (e.g., the Small Business Research Programs—see CRS Report R43695, *Small Business Research Programs: SBIR and STTR*). Agencies may also contract with businesses.

This In Focus includes a summary of selected federal agencies and programs that provide business assistance such as loans, business counseling, and other forms of technical assistance to health and medical businesses. These programs vary in scope, funding levels, and availability, and their relevancy to meeting the needs of specific businesses also varies. This In Focus does not represent a comprehensive list of all potentially relevant federal assistance programs for health and medical businesses, nor does it cover federal contracting preferences and tax incentives.

For broader business assistance opportunities, including those from the Small Business Administration (SBA), see CRS In Focus IF12449, *Connecting Constituents with Federal Assistance for Businesses*.

Specific information about health care facilities is available in CRS Report R48081, *Sources of Federal Funding for Health Care Facilities: Frequently Asked Questions*.

Health and Human Services (HHS)

Office of Small and Disadvantaged Business Utilization (OSDBU)

HHS partners with the SBA to support small business contractors. OSDBU, in conjunction with the SBA, supports several programs for small businesses:

- The 8(a) Business Development Program supports small businesses owned by socially or economically disadvantaged people or entities competing for federal contracts. The SBA supports eligible entities through federal contracting opportunities, training, and technical assistance. Several CRS publications discuss the 8(a) Business Development Program, including CRS In Focus IF12458, *The SBA's 8(a) Business Development Program*.
- The HUBZone program supports small businesses located in historically underutilized business areas. HUBZone-certified businesses are eligible for contract set-asides and sole-source awards. For more information, see CRS In Focus IF12428, *The SBA's Historically Underutilized Business Zone (HUBZone) Program*.
- According to the HHS website, “each year, the federal government aims to award at least 5% of all federal contracting dollars to Service-Disabled Veteran-Owned Small Businesses (SDVOSB).” Businesses must be certified by the SBA under the SDVOSB program and may receive contract set-asides and sole-source awards.
- HHS sets aside certain federal contracts for eligible Women-Owned Small Businesses and Economically Disadvantaged Women-Owned Small Businesses. Entities must certify their eligibility through the SBA.
- OSDBU hosts the Small Business Customer Experience Portal, a database providing information on HHS programs—including contracting opportunities and potential engagement opportunities with industry partners—and a Small Business Directory.

National Institutes of Health (NIH)

The NIH Seed Fund is another SBA partnership that provides funding for small businesses through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs.

- SBIR contracts are funding opportunities available to small businesses that meet specific needs, as identified by NIH.
- SBIR and STTR grant funding opportunities are for small business entrepreneurs seeking non-dilutive funding (capital received that does not require giving up equity or ownership) for early-stage R&D. STTR grants require partnership with nonprofit research institutions.
- The Small Business Transition Grant is awarded to early-career scientists and professionals with research, technology development, and/or health care delivery

skills and experience. Applicants must have limited entrepreneurial and independent (non-mentored) research leadership experience.

- The Technical and Business Assistance Programs help small businesses identify and address certain product development needs. Funding can support assistance with product sales, intellectual property protections, market research, development of regulatory and manufacturing plans, and access to technical and business literature available through online databases.

Food and Drug Administration (FDA)

FDA research programs provide initiatives encouraging small businesses to meet federal research and development needs, increase private sector commercialization of innovations derived from federal R&D, and foster and encourage participation by minority and disadvantaged persons in technological innovation.

Information on small business assistance available through several FDA centers is available through the FDA's website. Examples of FDA funding avenues small businesses may qualify for include the following:

- The FDA Broad Agency Announcement (BAA) for Advanced Research and Development of Regulatory Science is an example of an agency-wide BAA established to support R&D in regulatory science and innovation.
- The Center for Biologics Evaluation and Research Advanced Technologies Program supports development and adoption of advanced technologies to modernize biopharmaceutical manufacturing.
- The Office of Regulatory and Emerging Science provides funding for extramural medical countermeasures (MCMs) regulatory science research to promote MCM safety, efficacy, quality, and performance.

Centers for Medicare and Medicaid Services (CMS)

CMS does not provide grant or loan funding directly to businesses. However, as the agency overseeing Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace, CMS has some initiatives that may involve health and medical businesses.

In order to bill Medicare for services provided, providers of medical care and suppliers of durable medical equipment, prosthetics/orthotics, and supplies can obtain national provider identifiers and complete the enrollment process. Businesses creating or supplying services or items they want Medicare to cover may seek details about the Medicare coverage determination processes. See CRS In Focus IF13031, *Medicare Coverage: Background and Resources*, for more information.

The CMS Innovation Center, also referred to as the Center for Medicare and Medicaid Innovation, develops and tests health care payment and service delivery options to improve patient care, lower costs, and align payment

systems to promote patient-centered practices. Though participants in these pilot or demonstration programs are generally already Medicare providers, some opportunities (such as one current model to test healthy lifestyle interventions) more broadly include health care businesses, including technology companies. Businesses can search current models or sign up for updates.

CMS also hosts initiatives that may seek participation or feedback from businesses. For example, their Health Technology Ecosystem initiative includes a Medicare App Library seeking developer applications.

Health care businesses seeking to become Medicaid providers may enroll with their state Medicaid agencies.

Biomedical Advanced Research and Development Authority (BARDA)

BARDA partners with industry to support the late stage development of MCMs in order to respond to health security threats. Threats include chemical, biological, radiological, and nuclear accidents; incidents and attacks; pandemic influenza; and emerging infectious diseases.

Funding to support industry partners specializing in developing MCMs may be available through the BARDA BAA.

Additional Resources

Congressional offices and businesses may consult several additional potential sources of funding or training, including the following:

- State and local government agencies are often involved in administering grants and incentives for economic development purposes. Constituents can contact their state economic development organizations for additional assistance, incentives, or loan options. They can also contact their state health departments or view listed funding opportunities.
- The resources at USA.gov broadly identify the government financing programs that may be available to help finance an existing business.
- The Rural Health Information Hub provides state and topical guides that discuss funding opportunities. These guides are focused on rural areas and funding may or may not be available to for-profit organizations.
- The SBA's Small Business Development Centers provide free counseling, training, and resources to small business owners and entrepreneurs. See CRS In Focus IF12402, *The SBA's Small Business Development Centers Program*.
- SCORE, an SBA partner organization, is a nonprofit association dedicated to helping nonprofits and small businesses achieve their goals through education and mentorship.

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