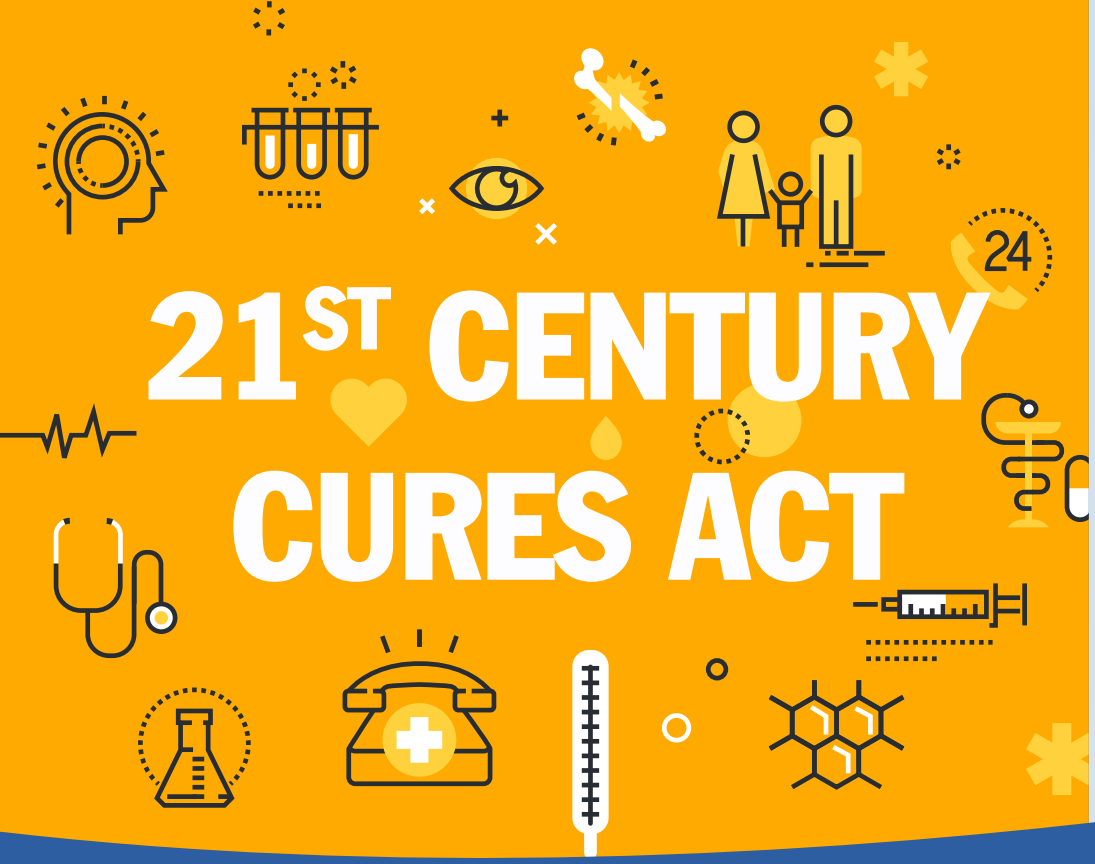

CCMC®

IssueBrief

March 2018

Discovery, Development and Delivery:

The 21st Century Cures Act

Promising big money for cancer and brain research, faster approval for new drugs and funding for opioid abuse treatment, the 21st Century Cures Act was legislation everyone could support. President Barack Obama signed the $6.3 billion law in December 2016—his final month in office. He then handed the official signing pen to Vice President Joe Biden, whose late son's death from brain cancer inspired widespread support for the measure.

"The 21st Century Cures Act is a sweeping law, passed with nearly unanimous bipartisan support," says MaryBeth Kurland, CAE, CCMC's chief executive officer. "It's designed to accelerate the discovery, development and delivery of cures and treatments for all Americans."

Those three pillars—discovery, development and delivery—provide a high-level framework for examining the significant changes the 21st Century Cures Act (the Cures Act) will make in how the nation develops treatments and uses health information technology to expand the "cures" landscape.

"The 21st Century Cures Act is a sweeping law, passed with nearly unanimous bipartisan support. It's designed to accelerate the discovery, development and delivery of cures and treatments for all Americans."

— MARYBETH KURLAND, CAE
CEO, COMMISSION FOR CASE MANAGER CERTIFICATION

> ***"This funding will spur new cures and treatments, and that's critical for case managers. Staying aware of some of the emerging breakthroughs in these areas is going to be really important in your role."***
>
> — JANET MARCHIBRODA, DIRECTOR, HEALTH INNOVATION
> EXECUTIVE DIRECTOR, CEO COUNCIL ON HEALTH AND INNOVATION
> BIPARTISAN POLICY CENTER

"The 21st Century Cures Act is a big package," says Janet Marchibroda, director of the Bipartisan Policy Center's Health Innovation Initiative and executive director of its CEO Council on Health and Innovation. "A lot of the support for the Cures Act related to the almost three years of work leading up to its passage, including town halls and public meetings, with collaboration from both democrats and republicans."

Center stage: Discovery

By far the largest outlays in the Cures Act are for new research funding for the National Institutes of Health. Over the next decade, the NIH will spend $4.8 billion on four initiatives: precision medicine, brain research, the "Cancer Moonshot" and adult stem cell research.

But the Cures Act also streamlines *how* that research is carried out. It includes measures to:

- Cut through administrative red tape that can delay clinical trials;
- Allow researchers to collaborate with one another more;
- Improve data sharing among researchers;
- Strengthen privacy protections for research volunteers; and
- Enhance research that includes diverse populations.[1]

Jump-starting research and development of new treatments is at the core of the Cures Act. "It takes more than 10 years and more than $2 billion, on average, to bring new treatments to patients in the U.S.," Marchibroda says. While many other countries have been investing in research and development, the level of development—and efficiency—in the U.S. fell behind. "We have about 10,000 known diseases, but only treatments for about 500," she says.

From 20,000 feet, the Cures Act is a means to clear barriers to medical advancement, while opening the door for health information and data exchange to better support the work. "Many, many millions of Americans are suffering from Alzheimer's or Parkinson's disease, from neurological disorders and cancer, for which we have no cure," she says. "It takes investment and focus in the NIH and other agencies to make that happen."

Although the NIH funding must be approved by Congress for each budget year, support for research in the Cures Act has not waned since its passage, Marchibroda notes. "As you look at the budget activity, there's continued interest in supporting the NIH. That's important, because one study showed that more than 60 percent of the most important drugs on the market resulted from NIH-funded research grants," she says.

"This funding will spur new cures and treatments, and that's critical for case managers. Staying aware of some of the emerging breakthroughs in these areas is going to be really important in your role."

Research to find cures for "All of Us"

NIH's Precision Medicine Initiative garners $1.45 billion in total funding. Referred to as the "All of Us" initiative,[2] it's laying the foundation to accelerate health research and enable individualized prevention and treatment findings. The initiative builds an entirely new data set, seeking information from a million individuals—including health claims information plus data on the biological, behavioral and environmental factors that affect health.

[1] The 21st Century Cures Act. National Institutes of Health. https://www.nih.gov/research-training/medical-research-initiatives/cures

[2] For more on the All of Us initiative, see https://allofus.nih.gov.

All of Us is intentionally gathering data from a diverse population. Once gathered, the data will be available to researchers in a de-identified format. The aim is to equip researchers to produce more targeted, individualized treatments.

"Traditionally, research has looked at the health of populations, not individuals," Marchibroda says. "Clinical trials tend to use a one-size-fits-all approach. The populations don't include patients with co-morbidities. They tend not to be the older or the younger patients. Often there are not as many women or minorities represented. They don't reflect the real world. But there is so much that can impact how we as individuals react to a medical product—our genetics, our lifestyle, the foods we eat, how much we exercise, and the environments in which we live."

Personalized data can be used to better fit treatments to the person, she notes. Over the past year, the All of Us initiative has actively engaged health providers, community health centers and the Veterans Health Administration to launch the data gathering effort. The national rollout of the All of Us program is expected to begin in the next few months, Marchibroda says.

"Precision medicine is now a therapeutic option for Americans," Marchibroda says. "But in many cases, reimbursement policies have not caught up with personalized therapies, and the cost of these therapies is not within reach. Case managers will need to understand reimbursement options available to patients who wish to undergo genetic screening and pursue precision medicine options, and then coach patients to help them pursue different treatments."

> ***"Case managers will need to understand reimbursement options available to patients who wish to undergo genetic screening and pursue precision medicine options, and then coach patients to help them pursue different treatments."***
>
> — JANET MARCHIBRODA
> DIRECTOR, HEALTH INNOVATION
> EXECUTIVE DIRECTOR, CEO COUNCIL
> ON HEALTH AND INNOVATION
> BIPARTISAN POLICY CENTER

Tackling the century's big health problems

In 2017 alone, about 1.7 million new cancer cases were diagnosed in the U.S. and more than 600,000 Americans died from the disease.[3] Research in Alzheimer's disease—the nation's sixth leading cause of death—has not succeeded in producing treatments that even slow its progress, much less find a cure. Other neurological disorders like Parkinson's disease also elude successful treatments.

The Cures Act provides more than $1.5 billion in funding for the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative. Its goal is to accelerate development of technology that helps researchers better understand how the brain works, which will, in turn, accelerate research to find cures for neurological diseases. In 2017, the NIH invested the first $260 million to fund research that will map whole brains in action, offer the ability to identify thousands of brain cells at once, and produce innovative brain scanners.[4]

The Cancer Moonshot is another major area of NIH funding under the Cures Act. Cancer research to develop vaccines, improve diagnostic tests and develop new treatments is already going forward. "This research has the potential to transform the field," Marchibroda says. In 2017, NIH awarded grants to 142 Cancer Moonshot research projects—spending $300 million of the $1.8 billion total funded through the Cures Act.[5]

A glide path for drug development

The Food and Drug Administration is responsible for testing new drugs to establish their safety and effectiveness. The FDA has long had a

[3] "Cancer Facts & Figures 2017." *American Cancer Society,* www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2017.html

[4] "NIH BRAIN Initiative builds on early advances." NIH announcement. Oct. 23, 2017. https://www.nih.gov/news-events/news-releases/nih-brain-initiative-builds-early-advances

[5] Cancer Moonshot. National Cancer Institute. https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative

process for "expedited review" of drugs to bring them to market faster, reserved for drugs that fulfill an unmet clinical need and, therefore, merit faster review. A study of drugs that have gone through expedited review between 1999 and 2012 found they provided greater health gains than those approved through conventional means. In short, the FDA has a solid track record for selecting the highest priority drugs to move through an expedited process.[6]

The Cures Act enhanced the FDA's review guidelines to further expedite the process and ease the requirements for drug approval. It also allows the FDA to use clinical biomarkers as surrogates for long-term outcomes data. Biomarkers are objective indications of a medical condition that can be accurately measured. Examples of biomarkers include pulse and blood pressure readings and results from blood chemistry or more complex lab tests.[7]

"When you review and approve a drug, you look at the long-term outcomes. Inherently, that takes a really long time," Marchibroda says. "Biomarkers can be used to select patients for inclusion in clinical trials, predict or identify safety problems, or reveal a pharmaceutical activity expected to predict an eventual benefit from a treatment."

The Cures Act acknowledges the value of biomarkers and expands the FDA's use of appropriate markers. "The FDA has the ability to qualify biomarkers for drug approval, but it must be transparent about the processes for doing so. All of that is important to manage the risk to patients of going down this road, so it's pretty important that case managers understand this," Marchibroda says. To date, the FDA has been working to draft guidance for how biomarkers are reviewed and approved for this purpose.

The Cures Act also allows patients to be more directly engaged as partners in the drug approval process. "In the benefit and risk assessment part of the drug approval process, many patient groups felt that the patient's voice wasn't really being heard," Marchibroda says. The law requires the FDA to make public statements regarding patient experience data that's submitted as part of any drug application. It must establish how patient experience data should be gathered and make clear how it will be used by the FDA. "Patients *want* to be engaged as partners in the drug development process," Marchibroda says.

Better use of health data is also now part of the drug approval process. "The federal government has

[6] Chambers, James D., et al. "Drugs Cleared Through The FDA's Expedited Review Offer Greater Gains Than Drugs Approved By Conventional Process." *Health Affairs*, vol. 36, no. 8, Jan. 2017, pp. 1408–1415., doi:10.1377/hlthaff.2016.1541.

[7] Strimbu, Kyle, and Jorge A. Tavel. *What are biomarkers?* U.S. National Library of Medicine, Nov. 2010. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3078627

Mental health measures in the 21st Century Cures Act

The Cures Act includes provisions to strengthen mental health and substance abuse prevention, treatment and recovery programs. The law provides $1 billion in funding over two years for states to enhance opioid abuse prevention, treatment and support. Nearly half of that was disbursed via grants to all 50 states in 2017 by the Substance Abuse and Mental Health Services Administration.[†] The funds help states expand the use of prescription drug monitoring programs, train providers to respond to opioid abuse more effectively, and put prevention programs in place. Marchibroda acknowledges progress on this front, but there's still a long way to go.

"The 21st Century Cures Act didn't tackle this issue enough to enable that information flow," she says. "There's a lot of policy discussion about it, and there are a number of bills out there. I'm confident that with all the focus on opioid abuse, we will see progress to enable the sharing of information in an appropriate way, that still ensures patient privacy."

[†] Bresnick, Jennifer. HHS Distributes $458M in 21st Century Cures Opioid Abuse Grants. Health IT Analytics, April 21, 2017. https://healthitanalytics.com/news/hhs-distributes-458m-in-21st-century-cures-opioid-abuse-grants

invested almost $40 billion in health information technology and electronic health records, and the vast majority of our hospitals and physician offices are now using them. Many of us are using all sorts of personal technology and apps to track our health. But none of that EHR or patient-generated data was considered by the FDA for drug approval. The old way of gathering patient experience of care was largely survey-based," Marchibroda says.

The Cures Act initiates the use of real-world evidence about patient experience. "Real-world evidence that you gain from claims and billing systems, electronic health records and patient-generated data can help those who approve and develop drugs to really understand how they're working in the wild—in the real world—with a diverse group of patients and in different practice settings."

Creating more data sources to support cures

The Cures Act doesn't eliminate the use of randomized control trials to test safety and effectiveness of drugs. But Marchibroda expects use of patient-generated data and information from EHRs will give the FDA further insight and "take us to the next level as we look at new discoveries." EHR and patient-generated data can also be used to assess medical technology and products for reimbursement. "Real-world evidence can tackle both," she says. "There's been a lot of discussion around how drug and reimbursement approval can work in parallel, so payers can understand the impact earlier. Understanding how a medical product, a drug or biologic can work in smaller populations, and earlier in the process, can be helpful for patients and payers." The FDA is developing a framework to evaluate the use of real-world evidence to support new indications or post-approval study requirements and is on track to complete its development by December 2018. It is collaborating with private-sector data initiatives on demonstration projects to test the ideas supporting that framework.

> ***"Increasing the availability of drugs—including generic drugs—will help create more competition in the marketplace, which can help make treatments more affordable and more accessible to patients."***
>
> — JANET MARCHIBRODA
> DIRECTOR, HEALTH INNOVATION
> EXECUTIVE DIRECTOR, CEO COUNCIL
> ON HEALTH AND INNOVATION
> BIPARTISAN POLICY CENTER

For case managers, rapid approval of new treatments, devices and drugs can more quickly bring interventions to patients. The FDA has already increased its drug approval rate; more than twice as many new drugs were approved in 2017 compared to 2016, and 1,027 generic drugs were approved in 2017—the highest annual rate in FDA history.

And that's good news for patients.

"Increasing the availability of drugs—including generic drugs—will help create more competition in the marketplace, which can help make treatments more affordable and more accessible to patients," Marchibroda says.

Gaining Congressional approval to use real-world evidence will not only affect the FDA's process. It will also support ongoing monitoring of the effectiveness and value of drugs, supporting patient decision-making.

"We're getting ready to see amazing things around how drugs work—their effectiveness and safety—earlier, based on observational data and real-world evidence that will augment randomized control trials. And that will help us solve a whole range of issues," Marchibroda says.

Better care delivery: Cure the data-entry blues

The adoption of electronic health records has placed a wealth of patient data in digital form. EHR use is intended to improve access to individual patient data when providers need it, as well as enhance quality improvement efforts. EHRs and the ability to track treatment and outcomes for populations also inform private- and publicly-funded provider reimbursement initiatives. In the transition of health care reimbursement

from paying for volume of services to paying for value-based results, these initiatives have also increased the administrative burden on providers to enter and track data electronically.

"There have been some unintended consequences to EHR adoption," Marchibroda says. Researchers say primary care physicians spend nearly two hours on electronic health record tasks for every one hour of patient care.[8] Emergency department doctors spend about 43 percent of their time on data entry, compared to 28 percent of time with patients.[9] The burden of reporting quality measures is estimated to require about 15 hours per week per physician.[10]

"Quality data submission can be quite time consuming, so we're seeing lower levels of productivity, higher operating costs and quite a bit of physician burnout," Marchibroda says.

The Cures Act calls for the Department of Health and Human Services to reduce this regulatory burden. Four work groups have been established to determine how to eliminate some reporting requirements—particularly those demanded under the Centers for Medicare & Medicaid Services' EHR Incentives program and its physician reimbursement programs, as well as reporting associated with the Hospital Value-Based Purchasing program and information systems certification.

> ***"Do you have access to the data you need, across the care continuum, for the various clinicians that provide care to your patients?"***
>
> — JANET MARCHIBRODA
> DIRECTOR, HEALTH INNOVATION
> EXECUTIVE DIRECTOR, CEO COUNCIL ON HEALTH AND INNOVATION
> BIPARTISAN POLICY CENTER

Providers are also frustrated that competing EHR platforms don't easily exchange information with one another—often termed interoperability. In the same way bank automatic teller machines can access an individual's bank account from another bank, a doctor should be able to get needed information from another provider's EHR securely and immediately.

One barrier to interoperability is information blocking, an intentional effort to block health information exchange by a vendor or provider. Although some industry experts say interoperability issues are only technical problems, research by the Office for the National Coordinator for Health IT shows information blocking is a real problem.[11]

The Cures Act puts the burden on EHR developers to certify they don't participate in information blocking. They must successfully test real-world use of their technology to demonstrate interoperability. They must also attest that they don't engage in information blocking and can face fines of up to $1 million for falsifying that attestation.[12]

"The law requires that within one year, the Department of Health and Human Services requires health IT developers to go through certification that they haven't taken these actions, but that is still in the process of implementation," Marchibroda says. In fact, none of the Cures Act's EHR reporting program steps have been implemented to date.

"The Office of the National Coordinator for Health IT (ONC) told Congress they didn't have the resources to carry out this program, but we think it's pretty important," she says. "The idea is to create more transparency through reporting criteria on measures related to security, usability and interoperability around health information exchange.

---

8 Arndt, Brian G., et al. Tethered to the EHR: Primary Care Physician Workload Assessment Using EHR Event Log Data and Time-Motion Observations. Annals of Family Medicine, Sept/Oct 2017. http://www.annfammed.org/content/15/5/419.full

9 Hill, Robert G., et al. 4000 Clicks: a productivity analysis of electronic medical records in a community hospital ED. The American Journal of Emergency Medicine, Elselvier, June 2013. https://www.sciencedirect.com/science/article/pii/S0735675713004051

10 Casalino, L. P., et al. "US Physician Practices Spend More Than $15.4 Billion Annually To Report Quality Measures." Health Affairs, vol. 35, no. 3, Jan. 2016, pp. 401–406., doi:10.1377/hlthaff.2015.1258.

11 Report to Congress: Report on Health Information Blocking. Office of the National Coordinator for Health Information Technology. April 2015. https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf

12 Slabodkin, G. "ONC working on information blocking rule mandated by Cures Act." Health Data Management, Nov. 10, 2017. https://www.healthdatamanagement.com/news/onc-working-on-information-blocking-rule-mandated-by-cures-act

"Interoperability has been a big issue," she says. "Do you have access to the data you need, across the care continuum, for the various clinicians that provide care to your patients? Whether it's a hospital admission or discharge, seeing a specialist or having tests done—we need this. We've been talking about it for a long time, and we aren't there yet."

Barriers to interoperability include the lack of a business case for health systems and EHR vendors. There is a cost associated with interoperability, and as the number of health data sources expand, so does the complexity of creating interfaces that work across all systems.

Federal regulators have also hit road blocks when it comes to agreement on and adoption of common standards for health information exchange. Those standards—like patient identifiers and uniformity of how data is arranged—are critical for information to seamlessly move from one record to the next. It's a tricky balance to ensure patient information is secure while still allowing vendors to innovate and improve how EHRs function.

One bright spot is broad support in the EHR industry for the ONC's draft Trusted Exchange Framework and Common Agreement (TEFCA)[13]. Introduced in January 2018, the ONC will review public comments and move quickly to finalize the policies, procedures and technical standards in TEFCA that are necessary to advance the unified on-ramp to interoperability envisioned by the Cures Act.

Affirming patients' right to health information

Patient access to health information is also affirmed in the Cures Act. Although previous laws required providers (that used certified EHRs) to make individual records available to patients, providers have not always made it simple for patients to access their own data.

"The law didn't need to change, but this was a symbolic act on the part of Congress—that the Department of Health and Human Services should encourage partnerships with the goal of offering patients access to their health information, and educate providers on ways to provide that access," Marchibroda says. (To read more about this topic, see CCMC's March 2016 issue brief, *P is for Portability.*)

"I think these health IT provisions will have the most impact on case managers' day-to-day work," she says. "They will help to alleviate the frustration of not knowing a client's previous diagnoses, or what medical products or prescriptions they're using, what allergies they have, or what lab and radiology tests they've done. Interoperability supports care coordination, which is such a key component of the case manager's work. Implementation of these measures should provide more supportive data for case managers to help clients meet their health care goals."

> ***"Health IT and technological advances are tools case managers can use to better inform and better serve clients. For all of us, the Cures Act—we hope—will enable new treatments, new ways to leverage data, and the promise of new cures."***
>
> — MARYBETH KURLAND, CAE
> CEO, COMMISSION FOR CASE MANAGER CERTIFICATION

Advances in technology—data interoperability, new treatments and devices—support the core work of case managers, says CCMC's Kurland. "Technology grabs our attention, and the idea of precision medicine initiatives to personalize treatments is truly exciting," she says. "Health IT and technological advances are tools case managers can use to better inform and better serve clients. For all of us, the Cures Act—we hope—will enable new treatments, new ways to leverage data, and the promise of new cures." ■

[13] For more on TEFCA, see https://beta.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement.

About the Experts

Janet Marchibroda
Director, Health Innovation Executive Director, CEO Council on Health and Innovation
Bipartisan Policy Center

MaryBeth Kurland, CAE
CEO, Commission for Case Manager Certification

JANET MARCHIBRODA is the director of the Bipartisan Policy Center's Health Innovation Initiative and executive director of its CEO Council on Health and Innovation. Her work focuses on advancing innovative strategies to improve health and health care, effectively using data and technology to improve the lives of individuals and accelerating medical innovation. She also supports the Centers for Disease Control and Prevention's efforts to improve immunization rates and combat the Zika virus.

Marchibroda previously served as IBM's chief health care officer for global business services and as chief operating officer for the National Committee for Quality Assurance. She served as chief executive officer of the eHealth Initiative, at the same time leading Connecting for Health, an initiative supported by the Markle Foundation and Robert Wood Johnson Foundation. She previously led stakeholder engagement activities for the National Coordinator for Health Information Technology within the Department of Health and Human Services. Marchibroda holds a master's degree in business administration with a concentration in organization development, from George Washington University.

MARYBETH KURLAND leads and sets the Commission's strategic mission and vision. She manages relationships with likeminded organizations and oversees business development as well as the Commission's programs, products and services. She works directly with the Board of Commissioners, building its corps of volunteer and subject-matter experts who directly support and evaluate certification and related services. Prior to becoming CEO, Kurland served as the Commission's chief operations officer, and was staff lead for the development and launch of the Commission's signature conference, the CCMC New World Symposium®.

Kurland brings extensive experience to her role, having served as executive director of organizations including the Association of Medical Media, Office Business Center Association International and the League of Professional System Administrators. She holds a bachelor's degree from the University of Delaware and is a member of the Institute for Credentialing Excellence, the American Society of Association Executives and the Mid-Atlantic Society of Association Executives. In 2011, Kurland was recognized as Association TRENDS Young & Aspiring Association Professional.

Commission for Case Manager Certification
1120 Route 73, Suite 200 • Mount Laurel, NJ 08054
(856) 380-6836 • ccmchq@ccmcertification.org
www.ccmcertification.org

WRITTEN AND PRODUCED BY HEALTH2 RESOURCES.

Join our community of professional case managers!