GCD Advocacy Forges Regulatory Breakthroughs in Managed Care & Disease Management

HMO Change of Ownership Rules

For one of our HMO clients, GCD’s MC & DM Group worked with the Health Care Financing Administration (“HCFA”) to clarify a long-standing interpretation of the change of ownership rules for Medicare+Choice plans. Previously, HCFA allowed an HMO corporation to transfer ownership in a Medicare plan only through a merger with another corporation. We convinced HCFA that a sale of assets transaction should also be allowed to transfer a Medicare plan. (A sale of assets structure allows a purchaser easily to limit the assumption of a seller’s liabilities.) The new interpretation made the sale of our client’s HMO possible. HCFA included the clarification in its June 29, 2000 final Medicare+Choice rule and even used our explanation and rationale. Assets sales are now specifically authorized by regulation.

Risk Adjustment Modification

Our MC & DM Group also worked with HCFA on behalf of one of the nation’s largest disease management vendors to obtain a payment refinement to the risk adjustment system that is in effect for Medicare+Choice plans. Our client’s proactive efforts paid off with the first significant amendment to HCFA’s risk adjustment policy. The payment refinement will recognize the impact of disease management on congestive heart failure (“CHF”), one of the most frequently billed inpatient diagnoses for Medicare. The cur-

In This Issue:

- GCD Advocacy Forges Regulatory Breakthroughs........................................1-2
- Final Medicare+Choice Regulations Released...........................................3
- On The Horizon...........................................................................................4

Continued on page 2
rent risk adjustment system would allow for an additional payment only if a CHF patient had been hospitalized. The refinement is needed to acknowledge the positive effects of disease management programs. While HCFA has not yet decided on the details, the CHF refinement will recognize the benefits of a disease management program and allow some additional payment even if the person has not been hospitalized, thereby reversing perverse financial incentives. The payment refinement is expected to be made beginning in 2002.

Recognition of Disease Management in Fee-for-Service Medicare

Our MC & DM Group also recently achieved a landmark result in Congress by assisting a disease management client to obtain the first recognition of disease management in fee-for-service Medicare legislation. We convinced several members of Congress to sponsor an amendment to the Rx2000 bill (proposing Medicare prescription drug coverage) that included coverage of disease management services via a demonstration vehicle. The bill was passed by the House of Representatives along a party line vote. While prescription drug legislation faces an uphill battle for ultimate enactment in an election year, our ability to get disease management services covered bodes well for next year, when the chance for passage of such laws may be greater. We have also prepared a White Paper on the rationale for covering disease management benefits through direct contracts with the government. This White Paper is available from GCD upon request.

State Medical Record Privacy Laws: California and Texas

GCD has been assisting our client, the Disease Management Association of America, or “DMAA” (the nation’s first and largest disease and population management professional organization), to obtain needed amendments to last year’s hastily drafted medical records privacy law in California, S.B. 19, that could have jeopardized the industry’s growth prospects, and we are working with physician groups in Texas to prevent potentially damaging new action there. In California, we have assisted DMAA in negotiating difficult compromises with organized medicare and the pharmaceutical industry, that we believe will soon lead to a full legislative solution to the previous problems. In Texas, GCD testified on DMAA’s behalf before committees of both houses of the legislature on medical information privacy laws, Internet privacy, disease management accreditation and licensure, and on-line medical liability issues, among others.

Federal Medical Record Privacy Laws: HIPAA

GCD has engaged in multiple meetings with high-level HHS officials on behalf of many of our clients to raise HHS’s level of awareness of the burdens and costs associated with HIPAA compliance.

In addition to improving HHS’s understanding of the impact of HIPAA on employers, health plans, providers, and disease managers, GCD was able to achieve a significant victory on DMAA’s behalf by ensuring that the proposed HIPAA privacy rules recognized disease management as a protected sphere of activity that will not require patient authorizations for access to critically important patient medical information. GCD has continued to advocate such protections for disease management in the final rules, which are scheduled for release in the fall.

GCD’s entire Health Law Group and HIPAA Task Force has been focused extensively in recent months on preparing our clients for the imminent release of HIPAA privacy and security regulations, and have begun to make template documents and consulting services available to clients, as well as more traditional legal advice.
Final Medicare+Choice Regulations Released

The Health Care Financing Administration (“HCFA”) released the final version of the Medicare+Choice (“M+C”) regulations on June 29, 2000. GCD has been actively monitoring the regulations and meeting with HCFA officials to understand their impact on the full range of our clientele, including HMOs, PPOs, providers, employers, health information technology and disease management organizations.

The final version of the regulations did not change significantly from the interim regulations released in 1998. Rather, HCFA attempted to clarify and, in many cases, ease compliance with the regulations.

For example, individuals who are enrolled in a health plan prior to becoming Medicare-eligible will now be permitted to continue with the health plan after becoming Medicare-eligible even if the individuals are outside the health plans’ approved M+C service area. In the interim regulations, such persons could not remain in the health plan. With the change, it will be more cost-effective for employers and M+C organizations (“M+COs”) to provide services to these individuals.

Further, the final M+C regulations clarify that providers have appeal rights only for adverse participation decisions, and not for more general changes in policies and procedures.

The final regulations also specifically state that preferred provider organizations will not be subject to the extensive quality assurance requirements to which health maintenance organizations are subject. PPOs now will be subject to the same quality assurance requirements as non-network M+C medical savings accounts plans and M+C private fee-for-service plans. This means, for example, PPOs will not be required to conduct performance improvement projects that apply to all plans. One of the biggest barriers to PPOs becoming M+COs was the extensive quality assurance requirements. PPOs do not traditionally gather such extensive data, so this change should encourage PPOs to join the M+C program.

Another example of easing compliance is that the final regulations permit a M+CO to use the same provider network for each of its plans, as long as each plan independently meets M+C access and availability requirements.

One final example of HCFA attempting to relax the burdens for M+COs is that organizations may be deemed to meet the M+C requirements if the organizations can show accreditation by an HCFA-approved accrediting body (e.g., NCQA or JCAHO).

Also, HCFA recently updated its M+C contracting guidelines. The new contracting guidelines now permit M+COs to include in provider policies and procedures what previously had to be included in the provider contract.

Requiring extensive provisions to be included in the provider contracts substantially increased M+COs and their contractors’ negotiations process as well as administrative costs. Note, certain provisions such as requirements for complying with Medicare rules must still be included in the provider contract.

Finally, HCFA has provided the ultimate encouragement for health plans to reconsider the Medicare+Choice program. HCFA has increased reimbursement to M+COs, and a new bill hopes to increase the reimbursement even more. After having made a significant commitment to the Medicare+Choice program, it appears HCFA is determined to make it work.

In sum, the final M+C regulations are very similar to the interim regulations. To the extent they are different, HCFA has attempted to ease compliance burdens so as to make offering M+C plans more attractive to commercial health plans. In light of the recent mass exodus from the M+C program, it is likely HCFA will continue to modify the regulations and issue policy statements to encourage participation in the Medicare+Choice program. It will be critical for health plans, providers, and administrative services providers to monitor continuously the changes to the Medicare+Choice program and the effects of those changes upon these entities.

Promotional Material
On The Horizon

September 18, 2000

September 19, 2000
James M. Jacobson, *Law and Disorder in e-DM: Best Legal and Regulatory Practices for Improving Your Company’s Health Outcomes*, The Symposium on E-Healthcare Strategies for Chronic Disease Management, Marriott Desert Springs Resort & Spa, Palm Desert, California. This symposium is a summit meeting for innovators and is designed to showcase breakthroughs in Web-enabled emerging technologies focused on the care of chronic disease patients. For more information, visit www.ehealthcareconnections.com.

October 7, 2000

November 13, 2000
James M. Jacobson, *e-DM: Business and Privacy Legal Issues in Disease Management*, Disease Management Association of America (DMAA), 2nd Annual Disease Management Leadership Forum, Hyatt Regency Inner Harbor, Baltimore, Maryland. This comprehensive forum brings together the leading authorities on the future of chronic disease management and provides ideal networking opportunities for health plans, providers, and pharmaceutical companies, as well as vendors. For more information, visit www.dmaa.org.

November 13-14, 2000

From Managed Care to Care Management: New Strategies for the New Millennium


Recognized as one of the premier health care firms in the country, Gardner, Carton & Douglas’ representation as general counsel or special counsel to health care industry clients spans over 80 years and includes all 50 states. Our Health Law Group is grounded in both our corporate practice and our federal regulatory expertise. This broad experience gives us the perspective needed to resolve legal issues in an industry as dynamic and complex as health care.

The TechVentures Group (TVG), a highly focused team of more than 50 lawyers, has been created to address the issues of emerging Internet technology companies, as well as established businesses and health care organizations seeking to introduce e-commerce into their business strategy. The TVG consists of lawyers from our Corporate, Technology, International Practice, Human Resources/Labor, Telecommunications and Health Departments.

This newsletter is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to subjects mentioned here.

© 2000 Gardner, Carton & Douglas