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Legislative Bulletin……..……March 5, 2008

Contents:

H.R. 1424—Paul Wellstone Mental Health and Addiction Equity Act (*Patrick Kennedy, D-RI*)

Please note the Conservative Concerns beginning on page 7, and those highlighted throughout the bulletin.

Order of Business: The bill is reportedly scheduled to be considered on Wednesday, March 5th, subject to a likely structured rule. A summary of any amendments made in order under the rule will be provided in a separate RSC document.

Summary: H.R. 1424 would amend the Internal Revenue Code, the Public Health Service Act, and the Employee Retirement Income Security Act (ERISA) to require equity in the provision of mental health disorder benefits for group health insurance plans that offer both mental health benefits and medical and surgical benefits. Previously, the Mental Health Parity Act—first enacted in 1996, and extended in subsequent legislation until it lapsed in December 2007—required only that plans choosing to offer both mental health and medical and surgical benefits must have equal annual and lifetime limits on coverage for both types of treatments. Specific details of the federal mandates in the bill include the following:

Treatment Limits and Beneficiary Financial Requirements: H.R. 1424 would require group health plans to offer the same financial benefit structure for both mental and physical disorders. The federal mandate would apply to overall coverage limits on treatment as well as deductibles, out-of-pocket limits, and similar beneficiary financial requirements.

Expansion of Definition: The bill would expand the definition of "mental health benefits" subject to the federal mandate to include substance abuse and disorder treatments. (See *Additional Background* section below.)

Minimum Scope of Benefits: H.R. 1424 would require all group health insurance plans offering mental health benefits to offer coverage for any mental health and substance-related disorder

included in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders. (See *Additional Background* section below.)

Out-of-Network Benefits: The bill would mandate plans that offer out-of-network insurance coverage for medical and surgical benefits to provide out-of-network coverage for mental health benefits, and at the same benefit levels. This provision exceeds the standards required by the Office of Personnel Management for insurance carriers participating in the Federal Employee Health Benefits Program (FEHBP); plans offered through the federal program need only provide mental health parity with respect to in-network benefit packages.

Increased Cost Exemption: H.R. 1424 would raise the level at which employers whose health insurance costs rise as a result of implementing mental health parity in benefits may claim an exemption from the federal mandate. The bill would exempt employers whose costs due to mental health claims rise by more than 2% in the first year of implementation, and by more than 1% in subsequent years. The more limited version of the Mental Health Parity Act first enacted in 1996 exempted employers whose claim costs rose 1%. Employers with fewer than 50 workers would be exempt from federal mandates under the legislation.

Federal Pre-emption: H.R. 1424 would not preclude states from imposing on employers who offer group health insurance coverage more stringent requirements with respect to "consumer protections, benefits, methods of access to benefits, rights, or remedies." This provision constitutes a significant variation from past federal policy with respect to employer-provided health insurance dating to ERISA's enactment in 1974. (See *Additional Background* section below.)

Random Federal Audits: The bill would require the Department of Labor to conduct annual audits of a random sample of group health insurance plans to ensure compliance with the federal mandates included in H.R. 1424.

GAO Study: The bill would require a study by the Government Accountability Office evaluating the law's impact on the cost of health insurance coverage, access to mental health care, and related issues.

Medicaid Drug Rebate: The bill would increase the rebate required of pharmaceutical companies offering single source (i.e. protected under federal patent laws) and innovator multiple source (i.e. formerly protected under federal patent law, but now subject to generic competition) pharmaceuticals in the Medicaid program from at least 15.1% of the Average Manufacturer Price (AMP) to at least 20.1% of the AMP. The increase would apply for the years 2009 through 2015. (See *Additional Background* section below.)

Specialty Hospitals: H.R. 1424 would impose additional restrictions on so-called specialty hospitals by limiting the "whole hospital" exemption against physician self-referral. Specifically, the bill would only extend the exemption to facilities with a Medicare reimbursement arrangement in place at the time of the bill's enactment, and generally prohibit facilities from expanding their total number of operating rooms or beds. Facilities may be able to expand their number of beds by up to 50%, provided that a) the population within the area has

grown at more than double the national average over a five-year period; b) the facility has an above-average rate of Medicaid admissions when compared to the statewide average; c) the facility is located in a state with average bed capacity below the national average; and d) average bed occupancy within the area is at least 80%. The bill also imposes additional reporting and related requirements regarding the nature of physician ownership arrangements. (See *Additional Background* section below.)

Additional Background on ERISA Pre-Emption: The Employment Retirement Income Security Act (ERISA) has served as the primary federal standard for the regulation of employee benefit plans since its enactment in September 1974 as Public Law 93-406. One of its key provisions, Section 514 (29 U.S.C. 1144), states that ERISA "shall supersede any and all state laws insofar as they may now or hereafter relate to any employee benefit plan," except in limited instances. As Rep. John Dent (D-PA), then-Chairman of the House Labor Subcommittee and sponsor of the bill which became the ERISA statute, noted during debate on the conference report:

> I wish to make note of what is to many ***the crowning achievement of this legislation***, the reservation to federal authority the sole power to regulate the field of employee benefit plans. With the pre-emption of the field, we round out the protection afforded participants by eliminating ***the threat of conflicting and inconsistent state and local regulation***. [Emphasis added.]

The strong pre-emption provisions have been upheld by numerous federal courts since the enactment of ERISA more than 30 years ago. In 2004, the Supreme Court in the case of *Aetna Health Inc. v. Davila* (542 U.S. 200) ruled that a Texas state law permitting lawsuits against managed care companies could not be enforced against plans provided by private employers due to ERISA's pre-emption provisions and remedies already available under federal law. More recently, the Fourth Circuit Court of Appeals cited ERISA pre-emption as the basis for striking down Maryland's so-called Wal-Mart bill, which attempted to enact a "pay-or-play" mandate on large employers by requiring them to contribute a percentage of payroll expenses to their employees' health care.

Over more than three decades, ERISA pre-emption has permitted thousands of employers to offer group health insurance coverage to millions of workers nationwide without the fear of becoming bogged down in complex and conflicting health insurance regulations in the several states. This system currently provides more than 177 million Americans—more than half the national population—with health insurance coverage, according to Census Bureau data. If passed, H.R. 1424 would permit states to pass laws with more stringent consumer protections, and could subject group health insurance plans to those state laws, creating the first significant erosion of ERISA pre-emption since its enactment.

Additional Background on Scope of Mental Health Benefits: H.R. 1424 would incorporate into federal statute the Diagnostic and Statistical Manual of Mental Disorders as the basis for which group health plans offer coverage for mental health conditions. Specifically, the bill would require plans to cover any mental disorder listed in the most recent edition of the manual, currently in its fourth edition (DSM-IV).

A 1999 executive order signed by President Clinton incorporated DSM-IV into the Federal Employee Health Benefit Program (FEHBP), beginning in January 2001. However, the Office of Personnel Management requires FEHBP carriers to cover "all ***categories of…conditions***" within DSM-IV, while H.R. 1424 requires overage of "***any mental health condition***"—a more expansive requirement for plans. Moreover, plans offering coverage within FEHBP are permitted discretion to require an "authorized treatment plan" based on medical necessity—but are given no discretion to determine necessity under H.R. 1424. The Office of Personnel Management has estimated that implementation of the executive order increased premium costs by 1.64% for fee-for-service plans participating in FEHBP.

The DSM-IV standards, first published in 1994 and revised slightly in 2000, include a wide variety of classifications for mental disorders, several of which are considered by some in the psychiatric community to have dubious value. In addition, the number and breadth of declared psycho-sexual disorders included in the DSM have sparked controversy between homosexual activists and traditional values supporters. Among the more troubling diagnoses incorporated into DSM-IV are:

- Nightmare disorder;
- Circadian rhythm sleep disorder (jet lag type);
- Caffeine-induced sleep disorder;
- Caffeine intoxication;
- Substance-induced sexual dysfunction;
- Gender identity disorder;
- Transvestic fetishism; and
- Pedophilia.

Under H.R. 1424, employers offering group coverage would be required to provide benefits related to these and similar diagnoses included in DSM-IV.

The expansive definitions of mental disorders included in DSM-IV have led to charges that psychiatric diagnoses have become politicized. In response, the American Psychiatric Association, which publishes the DSM guidebook, included the following explanation on its website:

> Q: Aren't some of the diagnoses included in the DSM there for political reasons?
> A: Decisions to include a diagnosis in the DSM are based on a careful consideration of the research underlying the disorder. This is not to say that decisions are made without regard to other considerations. ***Scientific data cannot be interpreted in a vacuum. Sociological and other considerations must also be taken into account.*** For example, each proposed new diagnosis carries with it the risk of making a false positive diagnosis (i.e., making a diagnosis when no disorder is present). Since false positives can never be completely eliminated, we must consider

> instead how to balance the advantages of including the diagnosis in the DSM (e.g., increased detection of a treatable disorder with consequent reduction in morbidity and cost to the patient, his or her family, and to society at large) against the risks of making a false positive diagnosis (e.g., risk of stigmatization, cost and potential morbidity of unnecessary treatment, etc.). However, the overall driving force in the decision to include or exclude a potential diagnosis from the DSM is the availability of scientific data. [Emphasis added.][1]

The American Psychiatric Association is tentatively scheduled to publish the fifth version of its Diagnostic and Statistical Manual of Mental Disorders (DSM-V) in 2011 or 2012, and any new disorders included in the revised version will be included in the federal mandate under the provisions of H.R. 1424.

Additional Background on Specialty Hospitals: The past few years have seen the significant growth of so-called specialty hospitals. These facilities, which generally concentrate on one medical practice area (often cardiac or orthopedic care), are often able to provide higher-quality care than general hospitals due to their focused mission. Critics of specialty hospitals claim that, by "cherry-picking" the best—and therefore most lucrative—candidates for surgical procedures, they siphon off revenues from general and community hospitals, threatening their future viability.

The ownership arrangements of many specialty hospitals have also been questioned. While federal law against physician self-referral prohibits doctors from holding an ownership stake in a particular department of a hospital facility, the "whole hospital" exemption permits physicians to hold an ownership stake in an entire facility. Because many specialty hospitals are physician-owned in whole or in part, some critics believe that physicians owning a stake in a specialty hospital may be inclined to perform additional tests and procedures on patients due to a stronger profit motive.

In July 2007, Section 651 of H.R. 3162, the Children's Health and Medicare Protection (CHAMP) Act, proposed several modifications to the "whole hospital" exemption for physician self-referral. Most notably, the bill applied the exemption only to those facilities with Medicare provider agreements in place prior to July 2007—excluding new specialty hospitals or other facilities, including those currently under construction, from protection under the self-referral statute—and prohibited existing facilities from expanding their number of operating rooms or beds. While the bill passed the House by a 225-204 vote, the Senate has yet to take up the measure.

Amidst spiraling costs and uneven quality, some conservatives may believe that the health sector warrants more competition, not less: new entrants to introduce innovative techniques and practices improving the quality of care; greater transparency of both price and quality information, so patients can make rational choices about the nature of their treatment options; and a funding system that reduces where possible the distortionary effects of third-party payment and empowers consumers to take control of their health. Viewed from this perspective, opposition to undue and onerous restrictions on the specialty hospitals that have driven innovation within health care may strike many conservatives as a return to first principles.

[1] Available at http://www.dsmivtr.org/2-1faqs.cfm (accessed February 21, 2008).

Additional Background on Medicaid Drug Rebates: As part of a drug payment policy designed to ensure that Medicaid paid the "best price" available, the Omnibus Budget Reconciliation Act of 1990 included provisions requiring manufacturers of pharmaceuticals desiring to offer their products to Medicaid enrollees to enter into rebate agreements with the Secretary of Health and Human Services (HHS). As of 2003, over 550 manufacturers have entered into rebate agreements, which apply to all pharmaceuticals separately billed to Medicaid. In 2005, states reported receiving $11.1 billion in federally required drug rebates, constituting 26% of all outpatient pharmaceutical spending. In addition, many states have their own additional rebate policies in effect; in 2005, 22 states reported collecting an additional $1.3 billion in supplemental rebates. However, a 2005 survey by the non-partisan Kaiser Family Foundation reported that nearly half of states surveyed (17 of 37) do not return their rebates to Medicaid, choosing instead to apply rebates to the general fund to finance other state spending.[2]

In determining rebate levels, federal law establishes two classes of pharmaceuticals. For single source drugs (those still under federal patent protection) and "innovator" multiple source drugs (those formerly marketed under a patent, but where generic competition now exists), rebate amounts are determined by comparing the Average Manufacturer Price (AMP) to the "best price"—the lowest price offered by the manufacturer to any retailer, wholesaler, or other entity. The basic rebate is equal to either 15.1% of the AMP or difference between the AMP and the "best price," whichever greater. Additional rebates for these drugs are required if their price rises faster than inflation, as measured by the consumer price index for urban areas. For "non-innovator" multiple source (i.e. generic) drugs, rebates are equal to 11% of AMP; "best prices" are not considered, and there are no additional rebates linked to price inflation.

The Deficit Reduction Act of 2005 (DRA) made several changes related to the Medicaid rebate system, particularly with respect to reporting of prices used to compute the pharmaceutical rebates owed. Specifically, DRA required states to report data regarding certain physician-administered outpatient pharmaceuticals, in an attempt to ensure that rebates for chemotherapy and other drugs administered in physician settings were properly paid. In addition, the DRA required that, for manufacturers who both produce a brand-name drug and license another manufacturer to produce a generic version, that the manufacturer-reported price include the price of these "authorized generics." In its cost estimate for DRA, CBO scored these changes as generating $220 million in additional federal revenues over five years, and $720 million over ten years.

Additional Background on Senate Legislation: On September 18, 2007, the Senate passed its version of the Mental Health Parity Act. This legislation, S. 558, sponsored by Sen. Pete Domenici (R-NM), contains significant variations when compared to H.R. 1424. Specifically, the Senate-passed language:

- Retains ERISA pre-emption for the large employers (those with more than 50 employees) subject to the law—states would not have the option of enacting more stringent and conflicting laws and regulations;

[2] Kaiser Family Foundation, *State Medicaid Outpatient Prescription Drug Policies: Findings from a National Survey, 2005 Update*, available online at http://kff.org/medicaid/7381.cfm (accessed March 3, 2008).

- Remains silent on codifying classes of mental disorders—the language does not require group health plans to offer coverage for all disorders under DSM-IV;
- Does not mandate an out-of-network coverage benefit—plans must offer out-of-network coverage only to the extent they do so for medical and surgical benefits, while the House bill mandates out-of-network coverage for all plans offering mental health benefits; and
- Permits group health insurance plans to utilize medical management practices, including utilization review, authorization, medical necessity and appropriateness criteria, and use of network providers—the House bill includes no such "safe harbor" for plans.

While some conservatives may still have concerns with the mandates imposed by the Senate legislation and the way in which these mandates would increase health insurance premiums, many segments of the business community have embraced the Senate compromise as a reasonable attempt to achieve the goal of both bills without eroding ERISA pre-emption or imposing undue restrictions on benefit plan design. Many of those same trade organizations are opposing H.R. 1424, as listed below, as a legislative over-reach that will impede their ability to offer quality coverage through group health insurance plans.

Committee Action: On March 9, 2007, the bill was introduced and referred to the Energy and Commerce Committee, the Education and Labor Committee, and the Ways and Means Committee. On July 18, 2007, the Education and Labor Committee reported the bill to the full House by a vote of 33-9. On September 26, 2007, the Ways and Means Committee reported the bill to the full House by a vote of 27-13. On October 16, 2007, the Energy and Commerce Committee reported the bill to the full House by a vote of 32-13.

Possible Conservative Concerns: Numerous aspects of this legislation may raise concerns for conservatives, including, but not necessarily limited to, the following:

- Increase Health Insurance Costs. As noted below, CBO estimates that H.R. 1424 would impose mandates on private insurance companies totaling $3 billion annually by 2012. These costs will ultimately be borne by employers offering health insurance and employees seeking to obtain coverage. Moreover, by increasing the cost of health insurance, H.R. 1424 will lead directly to an increase in the number of uninsured Americans.

- Private-Sector Mandates on Small and Large Businesses. As detailed below, the bill contains multiple new federal mandates on the private sector, affecting the design and structure of health insurance plans. Among other mandates, the bill would require plan sponsors to provide out-of-network benefits for mental health services if the sponsors provide out-of-network benefits for medical and surgical services, exceeding the standard mandated of insurance carriers participating in the FEHBP.

- Decrease in Mental Health Coverage. While the bill imposes several new federal mandates on those employers who *choose to offer* mental health coverage, there is nothing in H.R. 1424 that would impose a mental health mandate on all group health plans. Thus H.R. 1424 could have the perverse effect of actually *decreasing mental*

health coverage, by encouraging employers frustrated with the bill's onerous burdens to drop mental health insurance altogether.

- Intergovernmental Mandate. The bill would pre-empt state laws governing mental health coverage that conflict with the bill—but would not pre-empt laws providing more stringent consumer protections for employees. Additionally, the Congressional Budget Office (CBO) notes that some state and local governments would face increased costs for health insurance provided to their employees. However, as these higher costs would be in the form of increased insurance premiums borne by government entities, CBO does not consider these higher costs a direct intergovernmental mandate.

- Violation of UMRA. CBO estimates that the costs of the mandates to the private sector in the bill would be **at least $1.3 billion in 2008, rising to $3 billion in 2012** and thus exceed the annual threshold established in the Unfunded Mandates Reform Act or UMRA ($131 million in FY2007, adjusted annually for inflation).

- Codification of Treatment Mandate for Health Plans. H.R. 1424 would incorporate into federal law the DSM-IV classification definitions as the parameter of mental health treatment for health plans. The broad parameters included in the DSM-IV categories will obligate employers to cover "disorders" such as "jet lag" and "caffeine intoxication." The DSM-IV standards incorporated into federal law would also require employers to cover a broad array of sexual "disorders" that many conservatives may find objectionable, as noted above.

- Lack of Conscience Clause. H.R. 1424 would subject all employers with over 50 employees—including faith-based organizations—to federal mandates to cover all diagnoses under DSM-IV. The bill does not include an exemption for faith-based groups to exclude coverage of mental disorders, particularly psycho-sexual disorders, for which they have religious or moral objections.

- Erode Federal Pre-emption for Employers under ERISA. While H.R. 1424 does pre-empt state laws that conflict with the bill, it also explicitly permits additional state laws that provide more stringent consumer protections. This provision could undo a history of strict federal pre-emption dating to ERISA's enactment in 1974, creating a patchwork of laws across all 50 states with which major employers would have to comply. Some employers could decide to drop group health insurance coverage altogether rather than face a potentially conflicting array of state mandates and regulations to which they could be subjected under H.R. 1424.

- Lack of Medical Management Tools. H.R. 1424 does not include language explicitly permitting group health plans to negotiate separate reimbursement rates or provider payment rates and delivery service systems for different benefits. These tools would empower plans to utilize medical management practices in order to reduce claim costs.

- Decreased Access to Pharmaceuticals for Medicaid Patients. H.R. 1424 increases from 15.1% to 20.1% the minimum rebate amount which certain pharmaceutical manufacturers must pay to offer their drugs to patients within the Medicaid program. These tightened government price controls may cause some manufacturers to leave the program altogether, resulting in the loss of available prescription drugs for low-income beneficiaries.

- Restrictions on Specialty Hospitals. The bill would limit the "whole hospital" exemption under physician self-referral laws, such that any new specialty hospital—including those currently under development or construction—would not be eligible for the self-referral exemption, and any existing specialty hospital would be unable to expand its facilities, except under very limited circumstances. Given the advances which several specialty hospitals have made in increasing quality of care and decreasing patient infection rates, these additional restrictions may impede the development of new innovations within the health care industry.

- Budgetary Gimmick. In order to comply with PAYGO rules, H.R. 1424 would rely upon an increase in the Medicaid rebate for pharmaceuticals lasting from 2009 through 2015. The fact that the rebate levels are scheduled to increase and then return to current levels suggests that the legislative change proposed has as its primary motive the financing of the costs associated with an expansion of mental health parity. Some conservatives may believe this temporary increase violates the spirit, if not the letter, of the PAYGO requirement under House rules.

Administration Position: Although the Statement of Administration Policy (SAP) was not available at press time, reports indicate that the SAP will strongly oppose the legislation; a veto threat is possible but not certain. In September 2007, Labor Secretary Chao and HHS Secretary Leavitt wrote to the Senate HELP Committee expressing support for the Senate mental health legislation (S. 558), and stating "concern" with the bill introduced in the House (H.R. 1424).

Cost to Taxpayers: A final score of the substitute bill presented to the Rules Committee was not available at press time. However, according to a Congressional Budget Office (CBO) score of the bill as marked up before the Ways and Means Committee, H.R. 1424 would cost the federal government nearly $4 billion over ten years. Direct federal outlays would increase by $820 million through increased Medicaid costs. In addition, federal revenues would decline by more than $3.1 billion due to increases in the cost of health insurance, as employees with group coverage would exclude more of their income from payroll and income taxes.

The bill proposes to offset the costs outlined above by increasing the rebate rate required of drug manufacturers participating in the Medicaid program with respect to certain classes of pharmaceuticals. In addition, the bill places additional restrictions on physician-owned specialty hospitals. In July 2007, CBO scored similar provisions included in H.R. 3162, the Children's Health and Medicare Protection (CHAMP) Act as saving $3.5 billion over ten years by directing more patients from specialty hospitals and to general hospitals, due to CBO's belief that such a transition would result in overall savings to Medicare based on lower utilization rates for

outpatient services and related reimbursement changes. However, as noted previously, such savings may not be realized.

Does the Bill Expand the Size and Scope of the Federal Government?: Yes, the bill would authorize the Department of Labor to conduct random audits of plan to ensure they are in compliance with the bill's requirements, which according to CBO would require estimated appropriations of $330 million over ten years.

Does the Bill Contain Any New State-Government, Local-Government, or Private-Sector Mandates?: Yes, the bill would impose significant new mandates on private insurance carriers (and large employers who self-insure their workers) with respect to the structure and design of their benefit packages. CBO estimates that the direct costs of the private-sector mandates would total $1.3 billion in 2008, rising to $3 billion in 2012, significantly in excess of the annual threshold ($131 million in 2007, adjusted for inflation) established by the Unfunded Mandates Reform Act (UMRA).

In addition, the bill would also impose an intergovernmental mandate as defined by UMRA by pre-empting some state laws in conflict with the bill, but CBO estimates that this mandate would impose no significant costs on state, local, or tribal governments.

However, costs to state, local, and tribal governments would increase under the bill, for two reasons. First, the CBO cost estimate indicates that state spending for Medicaid would increase by $235 million between 2008-2012. Second, while state, local, and tribal governments that self-insure their workers would be able to opt-out of H.R. 1424's federal mandates, some governments that fully insure their workers (i.e. purchase coverage through an insurance carrier, as opposed to paying benefits directly) would see their costs rise under the legislation. CBO estimates that the bill would increase state, local, and tribal expenditures by $10 million in 2008, rising to $155 million by 2012. However, because these increased costs result from mandate costs initially borne by the private sector and passed on to the governments while purchasing insurance, CBO did not consider them intergovernmental mandates as such.

Does the Bill Comply with House Rules Regarding Earmarks/Limited Tax Benefits/Limited Tariff Benefits?: The Education and Labor Committee, in House Report 110-374, Part I, asserts that, "H.R. 1424 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9 of rule XXI."

Constitutional Authority: The Education and Labor Committee, in House Report 110-374, Part I, cites constitutional authority in Article I, Section 8, Clauses 1 (the congressional power to provide for the **general** welfare of the United States) and 3 (the congressional power to regulate interstate **commerce**). *(emphasis added)*

Outside Organizations: The following organizations are opposing H.R. 1424:

- Aetna;
- American Association of Physicians and Surgeons;
- American Benefits Council;
- America's Health Insurance Plans;
- Assurant;
- Blue Cross Blue Shield Association;
- CIGNA;
- Concerned Women of America (*potential key vote);
- Family Research Council (*potential key vote);
- National Association of Health Underwriters;
- National Association of Manufacturers (*key vote);
- National Association of Wholesaler-Distributors (*key vote);
- National Business Group on Health;
- National Restaurant Association;
- National Retail Federation (*key vote);
- Retail Industry Leaders Association;
- Society for Human Resource Management;
- U.S. Chamber of Commerce (*key vote).

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