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REPORT

The Importance of Stakeholder Participation in the Process to Define the 'Essential Health Benefits Package'



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Executive Summary

One of the main goals of health reform is to provide access to health benefits to approximately 32 million currently uninsured Americans.[1] Much has been written about who these people are likely to be and how most of the newly insured will obtain their coverage either through a newly expanded Medicaid program or through a private health insurance product likely to be offered either through state based exchanges or a national exchange administered by the Office of Personnel Management. However, not much has been discussed to date on exactly what will be included

[1] The Congressional Budget Office released its final cost estimate for the health care legislation on March 20, 2010, which states that the legislation is expected to ''reduce the number of nonelderly people who are uninsured by about 32 million, leaving about 23 million nonelderly residents uninsured.'' *See* Letter from the Congressional Budget Office to the Hon. Nancy Pelosi (Mar. 20, 2010), *available at* http://www.cbo.gov/ftpdocs/113xx/doc11379/AmendReconProp.pdf (last visited Dec. 3, 2010).

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in the ''essential health benefits package'' for private health plans offered in the exchange programs in order to provide coverage for this segment of the population.[2]

In fact, the initial focus to implement health reform has been on the medical loss ratio (''MLR'') for plan products participating in the state-based exchanges, *i.e.*, statutory rules regarding how much of the premium dollar for these plans needs to be for clinical services and for ''quality improvement activities'' as opposed to administrative overhead.[3] Another key piece relevant to the MLR equation that has yet to be defined is the ''essential health benefits package.''[4]

As discussed in detail below, the Patient Protection and Affordable Care Act of 2010 (''PPACA'')[5] says very little about exactly which health benefits will be included in, and which will be excluded from, the ''essential health benefits package.'' PPACA delegates the responsibility for the specifics of the ''essential health benefits requirements'' to the Secretary of the Department of Health and Human Services (the ''Secretary'' or ''HHS'') and attempts to take this issue out of the political maelstrom of Congress—not only at the time of enactment but in future years as well. This is in stark contrast to the way in which Congress has operated the benefits packages of other federal entitlement health benefits programs such as Medicare and Medicaid where coverage often is dictated by statutory amendments.[6]

The purpose of this article is to underscore the importance of stakeholder participation in the process for determining the ''essential health benefits package.'' To this end, this article explains in detail the specific statutory provisions in PPACA related to the scope of health benefits likely to be offered in the exchange programs for private health plans.[7] This article also describes the requirements and options for how the Secretary is supposed to create the ''essential health benefits package.''

This article further recommends the procedural process by which the Secretary should define the essential health benefit package within the context of the statutory framework. This recommended process is designed to maximize stakeholder participation.

Only health plan products that include the ''essential health benefits package'' are eligible to be offered in the new state exchanges and, therefore, are eligible for any available premium credits and subsidies. Even health plan products offered to large groups are impacted by which benefits are included in the ''essential health benefits package'' through a prohibition on lifetime and annual benefit limits.[8] Moreover, effective January 1, 2014, standards for Medicaid benchmark benefit packages and benchmark-equivalent coverage, as they relate to the uninsured newly-eligible recipients for Medicaid under PPACA, are required to provide at least the same ''essential health benefits package'' offered through the state exchange program.[9]

Also, which benefits will be included in this package will be significant to all of the stakeholders of health reform including consumers, providers, payers and manufacturers of products. Therefore, it is imperative that the Secretary's procedural process for establishing the definitions behind the ''essential health benefits package'' be inclusive, transparent, and efficient. This procedural process should include providing a meaningful opportunity for public comment in response to a ***proposed rule*** that actually delineates the proposed essential health benefits package, as well as through open forums and public hearings, in order to avoid replacing the political maelstrom of Congress with an executive branch maelstrom.

Consequently, the Secretary should start this rulemaking process now if there is going to be sufficient time for a full public rulemaking process to occur on this significant part of health reform.[10]

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[2] *See* PPACA § 1302. The term ''essential health benefits'' is different from the term ''minimum essential coverage'' defined in PPACA § 1501, which refers to the individual mandate to buy health insurance or pay a penalty that begins on January 1, 2014. The term ''minimum essential coverage'' broadly includes a listing of both private health insurance and public entitlement program options for satisfying the individual mandate requirement.

[3] Section 2718 of the Public Health Service Act (''PHSA''), as added by PPACA § 1001, requires health plans in the individual and small group market to spend at least 80% of premium revenue on medical claim costs and activities that improve health care quality, and health plans in the large group market to spend at least 85% of premium revenue on the same or provide premium refunds. On December 1, 2010, the Department of Health and Human Services (''HHS'') issued an interim final rule adopting and certifying the National Association of Insurance Commissioners (''NAIC'') model MLR regulation, in addition to addressing other implementation issues. *See* 75 Fed. Reg. 74864 (Dec. 1, 2010).

[4] PPACA §§ 1311(c)(1)(E), (g)(1).

[5] Pub. L. No. 111-148.

[6] *See e.g.*, for Medicare, § 1861 of the Social Security Act (**''SSA''**), Definitions of Services, Institutions, Etc.; *see also e.g.*, for Medicaid, SSA § 1905, Definitions.

[7] Benefits for newly-eligible Medicaid recipients are limited to the benchmark and benchmark-equivalent packages established under the Deficit Reduction Act of 2005 (Pub. L. No. 109-171, **''DRA''**), regardless of whether the state has opted to provide benchmark coverage as provided under the DRA. No federal matching is available for benefits beyond the benchmark or benchmark-equivalent definition. Effective January 1, 2014, PPACA § 2001 specifies new standards for Medicaid benchmark benefit packages and benchmark-equivalent coverage and uses the essential health benefits offered through the Exchange (*see* PPACA § 1302) as the benchmark. Effective upon enactment, PPACA amends benchmark-equivalent coverage to include prescription drug and mental health benefits as basic services. *See* PPACA § 2001(c)(2)(B). Mental health parity requirements apply to benchmark benefit packages or benchmark equivalent packages offered by an entity that is not a Medicaid managed care organization and that provides both medical/surgical and mental health or substance abuse benefits. Early Periodic Screening Diagnostic and Treatment (EPSDT) coverage is deemed to meet the mental health parity requirement. *See* PPACA § 2001(c)(3).

[8] *See* PPACA § 1001, adding PHSA § 2711. Effective January 1, 2014, ''[a] group health plan and a health insurance issuer offering group or individual health insurance coverage may ***not establish . . . lifetime limits on the dollar value of benefits*** for any participant or beneficiary; ***or . . . annual limits on the dollar value of benefits*** for any participant or beneficiary.'' PHSA § 2711(a). This prohibition does not prevent or prohibit health plans from ''placing annual or lifetime per beneficiary limits on specific covered benefits that are not essential health benefits.'' PHSA § 2711(b).

[9] *See* PPACA § 2001 (adding SSA §§ 1902(k)(1) and 1937(b)(5)).

[10] Public rulemakings may take several years to complete. As this package needs to be finalized before products can be offered through the state exchanges starting on January 1, 2014, it is not too early to begin this process now.

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I. An Overview of How a Health Benefits Package Works as to Coverage

Generally, a health benefits package includes three key components that shape the scope of benefits. The first component is enumerated benefits that are expressly included as covered benefits, such as inpatient hospital stays, so long as they are medically necessary.

The second component is the enumerated exclusions that are expressly excluded from covered benefits so that everyone knows what is not covered. An example of this in the Medicare program is the exclusion for ''hearing aids.''[11]

The third component is how the payer decides whether there is coverage for a procedure or product in the absence of either a specific enumerated benefit or exclusion. This third component is necessary because it is virtually impossible to address each and every potential covered benefit and excluded benefit in an enumerated fashion in a statute, regulation, or evidence of coverage.

An example is found in the Medicare program. One of the main Medicare enumerated exclusions is found in § 1862(a)(1)(A) of the Social Security Act, which states that ''no payment may be made under part A or part B for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.'' The inverse of this exclusion provides the general basis for Medicare coverage, namely that Medicare coverage includes only ''reasonable and necessary'' items and services.

The Medicare program often cites to this exclusion in its administration of claims for determining whether new medical technology and services are experimental and thus, neither reasonable nor necessary.[12] In making these determinations, medical directors often rely on medical evidence subscription services and other sources to decide whether a particular procedure or product should be covered in the absence of anything enumerated in the benefits package.

Coverage rules for health benefits also include coverage limitation rules regarding proper site of service. For example, the Centers for Medicare & Medicaid Services (''CMS'') permits Medicare coverage of certain surgical procedures only in hospitals, thereby excluding coverage in other settings, such as ambulatory surgical centers (''ASC'') and physician offices.[13]

In addition, coverage rules for health benefits include coverage limitation rules regarding the proper sequence of care. For example, the Medicare program requires a minimum three-day inpatient hospital stay before services can be covered for subacute care in a skilled nursing facility.[14] This three-day rule was designed to ensure that the Medicare benefit in a skilled nursing facility (''SNF'') was only for short-term care and not for long-term care.[15]

II. An Overview of the Parameters for Health Benefits in the 'Essential Health Benefits Package' of PPACA

By January 1, 2014, each state is required to establish an American Health Benefit Exchange (''Exchange'') that facilitates the purchase of Qualified Health Plans (''QHP''). PPACA § 1301 defines a QHP as ''a plan that . . . provides the essential health benefits package described in section 1302(a).''

PPACA § 1302(b)(1) specifies that ''the Secretary shall ***define*** the essential health benefits, except that such benefits shall include ***at least*** the following general categories and the items and services covered within the categories:

(A) Ambulatory patient services
(B) Emergency services
(C) Hospitalization
(D) Maternity and newborn care
(E) Mental health and substance use disorder services, including behavioral health treatment
(F) Prescription Drugs
(G) Rehabilitative and habilitative services and devices
(H) Laboratory services
(I) Preventive and wellness services and chronic disease management
(J) Pediatric services, including oral and vision care.''[16]

As one can see from the statutory language, the Secretary has the explicit authority to create the ''essential health benefits package'' that is at the epicenter of health reform.[17] This listing is the minimum. Indeed,

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[11] *See* SSA § 1862(a) (7), which states ''[n]otwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services . . . where such expenses are for . . . hearing aids or examinations therefore.''

[12] Guidance from a Medicare Contractor on medical necessity determinations provides the following description: ''If a service is considered investigational, experimental, or of questionable usefulness, the service may be denied as not reasonable and necessary. For example, acupuncture is considered experimental/investigational in the diagnosis or treatment of illness or injury. Claims will be denied because procedure/treatment has not been deemed ''proven to be effective'' by the payer.'' Highmark Medicare Services, A/B Reference Manual: Chapter 6 – Medicare Coverage, Medical Necessity, and Medical Policy, *available at* https://www.highmarkmedicareservices.com/refman/chapter-6.html (last visited Dec. 3, 2010).

[13] *See, e.g.*, 75 Fed. Reg. 46,301 (Aug. 3, 2010). Addendum E lists those surgical services for which a hospital will be paid only when provided in the inpatient setting because of the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. Similarly, Addendum EE lists surgical procedures excluded from Medicare payment in ambulatory surgical centers (''ASCs'') and represent, in part, services that CMS medical advisors determined pose a significant risk to beneficiary safety or would be expected to require an overnight stay when provided in an ASC.

[14] To qualify for Medicare reimbursement, a SNF stay must be preceded by an inpatient hospital stay of at least three consecutive days, not counting the date of discharge, which is within 30 days of the SNF admission. *See* SSA § 1861(i).

[15] *See* S.Rep. No. 404, 89th Cong., 1st Sess., reprinted in 1965 U.S.C.C.A.N. 1943, 1971, 1987.

[16] (Emphasis added).

[17] In contrast, PPACA § 1302(d)(1) describes the levels of coverage that must be included in the ''essential health benefits package.'' PPACA describes four levels of coverage as bronze, silver, gold, and platinum. These demarcations ad-

§ 2715 of the Public Health Service Act (''PHSA''), as added by PPACA § 1001, requires that information to consumers about their choices of products in the exchanges include a description of the coverage, including cost sharing for ''each of the categories of the essential health benefits described in subparagraphs (A) through (J) of section 1302(b)(1)'' and ''other benefits, as identified by the Secretary.'' Further, under PPACA § 1302(b)(5) of PPACA, payers have the legal authority to offer benefits that are ''in excess of the essential health benefits described [in PPACA § 1302(b)].''

PPACA's approach to define benefits through a minimum ''essential health benefits package'' differs significantly from the approach taken in the Medicare and Medicaid programs. For both entitlement programs, statutory provisions have governed, to a large extent, and in some detail, what the scope of benefits are, making Congress generally the author of benefits while leaving some room for interpretation and expansion at the agency and state level. In particular, for the Medicare program, Congress has been very specific about what benefits are included in the Medicare benefit package minimizing administrative discretion to expand.[18]

As the Medicaid program has been a state-run program with financing from both the state and federal governments, the nature of the Medicaid benefit package is slightly different and establishes essentially a floor of benefits that must be offered by state Medicaid programs for which federal matching dollars are available.[19] Similarly, the Medicaid program allows for certain optional benefits for which federal matching dollars are available.[20] As the federal government initially will pay 100 percent of the funding for the newly expanded Medicaid population, it will be interesting to see what role states will play in defining the ''essential health benefits'' that will serve as benchmark coverage required to be offered to these newly eligible Medicaid recipients.[21]

As described in **Exhibit A**, the language in PPACA for ''essential health benefits'' does not mirror the language that already exists for benefits provided in the Medicare program. For example, Congress did not use an umbrella term like ''medical and other health services'' found in the Medicare program to include physician services, therapy services and other practitioner services, as well as durable medical equipment, orthotics, prosthetics and supplies. Rather, Congress used umbrella terms that are slightly more descriptive to define benefit categories as represented by ''ambulatory patient services'' and ''rehabilitation and habilitation services and items.''

Through the use of umbrella terms that do not carry prior statutory history, the Secretary has more discretion to determine the scope of benefits included in the ''essential health benefits package.'' The lack of any statutory exclusions also creates more discretion. In some ways, allowing for this discretion, both immediate and prospective, should promote innovation by the Secretary in keeping the ''essential health benefits package'' current.[22] However, as described below, the Secretary's authority in this regard is not without limitations or procedural requirements.

III. The Requirement to Be 'Equal' to a 'Typical Employer Plan'

In creating this important ''essential health benefits package,'' PPACA § 1302(b)(2) provides that the Secretary ''shall ensure that the scope of the essential health benefits [described above] is equal to the scope of benefits provided under a typical employer plan, as determined by the Secretary.'' That means that the Secretary needs to determine what is a ''typical employer plan'' before finalizing the ''essential health benefits package.'' The Secretary then has to make a further determination that they are ''equal,'' an interesting standard to attempt to achieve.

The term ''typical employer plan'' is not defined in PPACA. To help determine what is a ''typical employer plan,'' PPACA instructs the Secretary, in the same statutory section, to look to the Secretary of Labor for advice and guidance. The Secretary of Labor regulates health plans offered by employers. Those health plans are diverse and can be either insured or self-funded and are subject to the Employee Retirement Income Security Act (''ERISA''), which is enforced by the Department of Labor.[23] The diversity of these plans suggest that there may not be a ''typical'' plan and that the process for determining ''the typical employer plan'' necessarily may involve some degree of subjectivity.

Notwithstanding, PPACA specifies that the Secretary of Labor ''shall conduct a survey of employer-sponsored coverage to determine the benefits typically covered by employers, including multiemployer plans, and provide a report on such survey to the Secretary.'' It has been reported that no discretionary funds were

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dress the ***actuarial value*** of the benefits provided under a qualified health plan, rather than actual benefits covered. In making these demarcations through analyses of actuarial value, the Secretary will affect benefit levels and designs, including cost-sharing provisions.

[18] For example, the Medicare program historically excluded coverage of preventive services and only recently has Congress expanded Medicare benefits by statute to include enumerated preventive services. Similarly, the Medicare program has limited coverage of mobility devices to ''in home'' use notwithstanding the impact that this limitation has on Medicare beneficiary access to their communities.

[19] SSA § 1905 defines the term ''medical assistance'' to establish the scope of mandatory benefits that a state Medicaid plan must provide and for which federal matching dollars are available.

[20] States have broad discretion to expand Medicaid eligibility beyond federal minimum standards to cover additional ''optional'' groups and services. Optional services include, among others, prescription drugs, case management, rehabilitative services, personal care services, and home and community-based services. Approximately 60% of Medicaid spending is estimated to be attributable to optional services. Anna Somers, Ph.D., et. al, Kaiser Commission on Medicaid and the Uninsured, *Medicaid Enrollment and Spending by ''Mandatory'' and ''Optional'' Eligibility and Benefit Categories* (June 2005), available at http://www.kff.org/medicaid/upload/Medicaid-Enrollment-and-Spending-by-Mandatory-and-Optional-Eligibility-and-Benefit-Categories-Report.pdf (last visited Dec. 3, 2010).

[21] *See* PPACA § 2001(a)(3).

[22] For example, in establishing the ''essential health benefits package,'' can the Secretary cover services where evidence-based conclusions are not yet available, similar to CMS's Coverage with Evidence Development? *See* Health Affairs, New Technology, Vol. 27, No. 6 (Nov./Dec. 2008).

[23] Pub. L. No. 93-406.

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appropriated to pay the Secretary of Labor to conduct this survey.[24] As a result, certain stakeholders are concerned that the quality of this survey may be jeopardized without such additional funding.[25]

Significantly, Congress directed the Secretary to look at employer-sponsored coverage rather than at the current health benefits packages of the public entitlement programs or even the current benefits packages offered to federal employees by the Office of Personnel Management or from the individual and small group market. The goal of PPACA is for consumers to gain access to the type of health benefits that the employer-sponsored plans provide to employees and dependents. The public entitlement programs, such as Medicare and Medicaid, generally have been locked in their original 1965 framework with changes in benefit structures requiring either statutory or administrative changes when necessary or desired.[26]

In making the final determination that the ''essential health benefits package'' is ''equal'' to a ''typical employer plan,'' PPACA § 1302(b)(3) further provides that the Secretary shall obtain a certification from the Chief Actuary of CMS that the ''essential health benefits'' meet the requirement that they are ''equal'' to the ''typical employer plan.'' Historically, the Chief Actuary has been involved primarily in matters related to the Medicare and Medicaid programs.

To ensure that Congress remains involved in benefit package issues, PPACA requires the Secretary to send a report to the appropriate committees of Congress containing the Chief Actuary's certification that the ''essential health benefits package'' meets the ''floor'' requirement established in the law that such package is ''equal'' to the ''typical employer plan.'' This reporting is not only for year one, but also when the Secretary periodically updates the ''essential health benefits package.'' It is likely that such reporting to the appropriate committees of Congress could trigger future legislative changes in the minimum benefits currently outlined in PPACA. At a minimum, such reports are likely to trigger Congressional hearings and oversight regarding the scope of the ''essential health benefits package.''

Finally, the Secretary needs to balance the legal parameters and societal needs to have adequate coverage with the fiscal constraints of what was expected in the Congressional Budget Office (''CBO'') scoring for premium tax credits and subsidies that would likely correspond with an ''essential health benefits package.'' If the package is too generous, it may alter significantly the fiscal impact of PPACA and result in significant premium increases in the marketplace. If the package is too stingy, then there could be underinsured people for medically necessary services.[27] Based upon the words in PPACA, the intention is for this health benefits package to be comprised of ''essential'' health benefits and not of desired health benefits that are not otherwise ''essential.''

In the meantime, to assist the Secretary in defining the ''essential health benefits package,'' the Secretary recently requested the Institute of Medicine (''IOM'') to undertake a study that will make recommendations on the criteria and methods for determining and periodically updating the benefits package.[28] The IOM will not define specific benefits or services to be included as ''essential health benefits,'' but will review how insurers determine covered benefits and medical necessity. The IOM intends to provide guidance to the Secretary on the policy principles and criteria the Secretary should ''take into account when examining QHPs for appropriate balance among categories of care; the health care needs of diverse segments of the population; and nondiscrimination based on age, disability, or expected length of life.''[29]

At this early stage, the IOM's guidance could significantly impact the scope of benefits ultimately included in the ''essential health benefits package.'' As a result, it also could influence the process for determining the ''typical employer plan'' as discussed above.

The IOM's work illustrates that, even at this early stage, it is important for stakeholders to engage in a dialogue now with HHS on the process for determining a ''typical employer plan'' for the purpose of determining the ''essential health benefits package.'' For example, this process includes how the Department of Labor survey process will be conducted and what will be included in the survey instrument. To that end, stakeholders should consider conducting their own survey as a means of checking and validating the government's survey results.

This process for determining the essential health benefits package also includes the scope and timing of the work the Secretary requested from the IOM. Through early dialogue, stakeholders can encourage the Secretary to maintain a transparent process and attempt to have stakeholder insights at each step.

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[24] The Congressional Research Service (''CRS'') issued a report summarizing all the discretionary provisions in PPACA for which appropriations are authorized. This report does not include any information about the ''essential health benefits package'' provision, or the employer survey required by the Secretary of Labor. *See* C. Stephen Redhead, CRS Report No. R41390, ''Discretionary Funding in the Patient Protection and Affordable Care Act (PPACA)'' (Sept. 2, 2010).

[25] In a letter to Nancy Ann DeParle, Director of the Office of Health Reform, dated May 18, 2010, dozens of consumer, labor and patient-centered organizations called on the Secretary of HHS to designate funding for the Secretary of Labor's employer survey. The letter states that ''the data necessary to define the package may not be forthcoming unless the survey of employer-sponsored coverage mandated by the PPACA is funded and conducted in a timely and rigorous manner.'' May 18, 2010 letter *available at* http://www.acscan.org/mediacenter/view/id/301 (last visited Dec. 3, 2010).

[26] Notable Medicare expansions include the ESRD benefit in the 1970s, a number of preventive benefits in the late 1990s (e.g., mammography), and the outpatient prescription drug benefit under Medicare Part D in 2003. In the Medicaid context, states have avoided some of the statutory restrictions on the scope of benefits (particularly as they relate to how these benefits are to be administered) through waiver and demonstration programs under SSA §§ 1115 and 1915.

[27] Similar issues occurred with the Federal Health Maintenance Organization (''HMO'') Act in 1973 resulting in amendments to make the HMOs a more fiscally balanced and competitive product. *See* Pub. L. No. 93-222; Pub. L. No. 94-460; and Pub. L. No. 95-559, 42 U.S.C. § 300e.

[28] Institute of Medicine, Determination of Essential Health Benefits, *available at* http://www.iom.edu/Activities/HealthServices/EssentialHealthBenefits.aspx (last visited Nov. 28, 2010).

[29] *Id*.

IV. Other Required Elements for the Secretary's Determination of the 'Essential Health Benefits Package'

PPACA § 1302(b)(4) provides a laundry list of additional required elements that the Secretary has to consider in making a final decision about the scope of the ''essential health benefits package.'' Each has its own substantive focus but generally they require the availability of benefits regardless of the consumer's age or health status. They also include some remnants of topics related to previous legislative initiatives to enact a patient's bill of rights.

The first required element is for the Secretary to ensure that ''such essential health benefits reflect an appropriate balance'' among the various broad categories of minimum (*i.e.*, essential) health benefits cited above in the statutory listing so that these minimum health benefits ''are not unduly weighted'' toward any one category.[30] From a practical perspective, it is unclear how the Secretary should address this particular element.

The second required element is for the Secretary ''not to make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life.''[31] In creating the ''essential health benefits package,'' it is unclear why there should be a reference here to reimbursement rates when reimbursement is not part of coverage. These are separate and distinct concepts.[32]

The third required element is for the Secretary to ''take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups.''[33] This element in particular appears to give the Secretary discretion to deviate from what may be a ''typical employer plan.''

Additional requirements make the Secretary ''ensure that health benefits established as essential not be subject to denial to individuals against their wishes on the basis of the individuals' age or expected length of life or of the individuals' present or predicted disability, degree of medical dependency, or quality of life.''[34] There also are specific references about coverage for emergency department services (both in and out-of-network)[35] and stand-alone dental plans.[36]

When periodically reviewing the ''essential health benefits package,'' the Secretary must assess ''whether enrollees are facing any difficulty accessing needed services for reasons of coverage or costs;'' and ''to address any gaps in access to coverage or changes in the evidence base;'' among other items. The goal of these provisions is to give the Secretary the opportunity to lead on coverage, with Congress being made aware so it can play a role directly or indirectly in this very important piece of the health reform puzzle.

V. Other Statutory Parameters for the 'Essential Health Benefits Package'

The Secretary will further influence the scope of the ''essential health benefits package'' through the process of standardizing both the summary of benefits and coverage. This includes uniform definitions of standard insurance terms and medical terms to facilitate both consumer comprehension and comparison.[37]

In addition, beginning in 2010,[38] ***all*** group health and individual health plans (including qualified health plans) are required to include certain preventative benefits without cost-sharing. Specifically, under PHSA § 2713 as added by PPACA § 1001, such plans must cover:

1. ''Evidence-based'' preventive items or services having an ''A'' or ''B'' rating from the U.S. Preventive Services Task Force;
2. Immunizations recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention;
3. Preventive care for infants, children, and adolescents as delineated in the comprehensive guidelines published by the Health Resources and Services Administration (HRSA); and
4. Preventive care and screenings for women as delineated in HRSA's comprehensive guidelines.[39]

PPACA made similar benefit expansions for the Medicare and Medicaid programs.[40] While these provisions are beyond the scope of this article, these provisions have the effect of ensuring that certain statutorily-mandated preventive benefits will be in the ''essential health benefits package.''

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[30] PHSA § 1302(b)(4)(A).

[31] PHSA § 1302(b)(4)(B).

[32] On December 22, 2009, the United States Court of Appeals for the District of Columbia Circuit issued a decision confirming the distinction between Medicare coverage and reimbursement by ruling that the Medicare statute precludes the Secretary of HHS from issuing a coverage determination that sets the reimbursement rate for a covered drug based on the ''least costly alternative.'' *Hays v. Sebelius*, No. 08-5508 (D.C. Cir., Dec, 22, 2009). *See* Stuart Gerson and Rob Wanerman, Epstein Becker Green Client Alert, ''D.C. Circuit Rules That Medicare Coverage Determinations Cannot Set Reimbursement Rates'' (January 6, 2010), *available at* http://www.ebglaw.com/showclientalert.aspx?Show=12278 (last visited Dec. 3, 2010).

[33] PHSA § 1302(b)(4)(C).

[34] PHSA § 1302(b)(4)(D).

[35] PHSA § 1302(b)(4)(E) requires that a ''qualified health plan'' must provide coverage for emergency department services ''without imposing any requirement under the plan for prior authorization of services or any limitation on coverage where the provider of services does not have a contractual relationship with the plan . . . ; and if such services are provided out-of-network, the cost-sharing requirement (expressed as a copayment amount or coinsurance rate) is the same requirement that would apply if such services were provided in-network.'' *Id.*

[36] PHSA § 1302(b)(4)(F) addresses specific operational issues for stand-alone dental plans, but does not speak to the scope of benefits itself.

[37] PPCA § 1001(1) (adding PHSA § 2715).

[38] Specifically, these provisions are effective for plan years beginning on or after September 23, 2010 (*i.e.*, 6 months after date of enactment of PPACA). *See* PPACA § 1004.

[39] PHSA § 2713(a).

[40] Specifically, any cost-sharing for Medicare covered preventive services recommended (rated A or B) by the U.S. Preventive Services Task Force will be eliminated and Medicare deductibles for colorectal cancer screening tests will be waived. *See* PPACA § 4104. In 2013, States will receive a one percentage point increase in the FMAP for offering Medicaid coverage of and removing cost-sharing for preventive services recommended (rated A or B) by the U.S. Preventive Services Task Force and recommended immunizations. *See* PPACA § 4106. At the same time, Medicaid payments for primary care services provided by primary care doctors will increase to 100 percent of the Medicare rate. *See* PPACA § 1202.

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VII. Procedural Requirements For How the Secretary Should Define the 'Essential Health Benefits Package'

It is generally understood that the Secretary has broad authority to promulgate regulations and sub-regulatory guidance in order to implement sections of PPACA. The Administrative Procedure Act (''APA'') regulates such activities.

However, in establishing the ''essential health benefits package,'' PPACA § 1302(b)(3) explicitly provides as follows:

> ''NOTICE AND HEARING.- In defining the essential health benefits described in paragraph (1), . . ., the Secretary [of HHS] shall provide notice and an opportunity for public comment.''

Although there is no explicit citation to the APA, this language should be considered as a reference to the notice of proposed rulemaking requirements found in APA § 553. That section requires notice in the *Federal Register* and an opportunity for the public to comment on the proposed rules ***before*** any provisions are considered final rules. This is in stark contrast to what the Secretary has been doing to date in the implementation of PPACA—publishing interim final rules where the public's opportunity to comment on a rule only begins after publication in final form. Under interim final rules, it is unclear whether and when the Secretary addresses the comments received or when the Secretary has to issue a final rule.[41] Consequently, the public's role in shaping policy under an interim final rule is marginalized significantly. Moreover, one cannot necessarily ''fix'' an interim final rule through sub-regulatory guidances like ''frequently asked questions.''

At times, the Secretary has issued a request for information followed by the publication of an interim final rule. An example was the Secretary's publication of regulations implementing the Mental Health Parity and Addiction Equity Act of 2008 (''MHPAEA'') which required health insurance issuers and group health plans that offer coverage of mental health and substance abuse treatment to make that coverage available in a manner comparable to the coverage offered for medical benefits.[42]

In April 2009, the Departments of Treasury, Labor, and Health and Human Services published a request for information seeking public comments on implementation of the MHPAEA. In response, over 400 comments were received.[43] Interim final rules then were published in February 2010 and became effective notwithstanding the receipt of more than 4,000 comments after the publication of the interim final rules.[44] The departments stated they were working on issuing final rules but the interim final rules remained effective.[45] Meanwhile, a coalition brought suit and argued that the departments violated the APA's notice and comment requirements by not issuing a proposed rule after the request for information so that the departments could have benefited from the public's comments on draft regulatory language before the departments made such regulatory language final. The rules were upheld on June 21, 2010, by the U.S. District Court for the District of Columbia which determined that the departments properly invoked the ''good cause'' exception to the notice and comment requirements based on Congressional authorization for the issuance of interim final rules, the need for prompt regulatory guidance, the interim nature of the interim final rules and the lack of evidence of delay by the departments.[46]

In contrast, we would argue that, by explicitly requiring ''NOTICE AND HEARING'' and ''notice and an opportunity for public comment'' in PPACA § 1302(b)(3), Congress expected the public to play a more substantive and meaningful role in the shaping of the ''essential health benefits package'' than what could be afforded either through interim final rulemaking or through a ''request for information'' followed by an interim final rule. Consequently, the public should have a meaningful opportunity to review and comment on the actual proposed ''essential health benefits package'' and not merely on general guidelines and parameters before anything becomes final.

Specifically, we would argue that the Secretary should provide a process for stakeholders to: (1) comment informally on the Department of Labor's survey process to determine the essential health benefits package (*e.g.*, through the Federal Register and through town hall meetings); and (2) comment formally through the proposed rulemaking process on the essential health benefits package actually being proposed as a result of this survey process. Indeed, transparency through open forums and hearings is explicitly required by this section of PPACA along with ''notice and an opportunity for public comment'' that should be meaningful and not marginalized by an interim final regulation.

All of this additional process on this particular topic should help achieve the public's buy-in with respect to the ''essential health benefits package'' ultimately adopted. It would be disappointing if the epicenter of health reform, i.e., the ''essential health benefits package,'' were to become embroiled in litigation and controversy. Nor can the issuance of sub-regulatory guidance overrule the Secretary's regulations defining the ''essential health benefits package.'' Furthermore, it

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[41] Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended SSA § 1871(a) to require the Secretary to ''establish and publish a regular timeline for the publication of final [CMS Medicare] regulations based on the previous publication of a proposed regulation or an interim final regulation.'' Further, ''[s]uch timeline may vary among different [CMS Medicare] regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but shall not be longer than 3 years except under exceptional circumstances.'' See Pub. L. No. 108-173 (Dec. 8, 2003). The provision also requires that CMS Medicare interim final rules may not continue in effect after the expiration of the timeline established by the Secretary ''unless the Secretary publishes (at the end of the regular timeline and, if applicable, at the end of each succeeding 1-year period) a notice of continuation of the regulation that includes an explanation of why the regular timeline (and any subsequent 1-year extension) was not complied with.''

[42] *See* Pub. L. 110–343, Div. C §§ 511-12 (Oct. 3, 2008).

[43] *See* 74 Fed. Reg. 19155 (Apr. 28, 2009).

[44] *See* 75 Fed. Reg. 5410 (Feb. 2, 2010).

[45] U.S. Department of Labor, News Release, *Statement of US Labor Secretary Hilda L. Solis regarding federal court ruling on mental health and substance abuse benefits* (Jun. 23, 2010), *available at* http://www.dol.gov/opa/media/press/ebsa/EBSA20100881.htm (last visited Dec. 3, 2010).

[46] *Coalition for Parity, Inc. v. Sebelius*, No. 10-527 (D.D.C. Jun. 21, 2010).

should be inappropriate to have time pass due to the other exigencies of implementation and then use that delay to justify the use of interim final regulations in this particular context.

As full proposed rulemaking takes time, it is imperative that the Secretary start this particular proposed rulemaking process as soon as possible. In that way, the required process in PPACA § 1302(b)(3) for having the Secretary define the ''essential health benefits package'' should not become an executive branch maelstrom or otherwise compromised.

Exhibit A
Possible Crosswalk of the "Essential Health Benefits" to Existing Medicare Benefits

''Essential Health Benefits''[47]	Medicare Benefits[48]
''Ambulatory patient services''	Ambulatory Surgical Centers Chiropractic Services (limited) Defibrillator (Implantable Automatic) Doctor Services Federally-Qualified Health Center Services Non-doctor Services Outpatient Hospital Services Outpatient Medical/Surgical Services & Supplies Rural Health Clinic Services Second Surgical Opinions Surgical Dressing Services Telehealth Urgently-Needed Care
''Emergency services''	Ambulance Services Emergency Department Services Travel (health care needed when traveling outside the United States) (limited)
''Hospitalization''	Blood Hospital Stays (Inpatient) Transplants & Immunosuppressive Drugs
''Maternity and newborn care''	NONE
''Mental health and substance use disorder services, including behavioral health treatment''	Mental Health Care (outpatient)
''Prescription Drugs''	Prescription Drugs
''Rehabilitative and habilitative services and devices''	Cardiac Rehabilitation Diabetes Supplies Durable Medical Equipment Eyeglasses (limited) Home Health Services Kidney Dialysis Services and Supplies Occupational Therapy Physical Therapy Prosthetic/Orthotic Items Pulmonary Rehabilitation Skilled Nursing Facility Care Speech-Language Pathology Services
''Laboratory services''	Clinical Laboratory Services Tests (e.g., x-rays, MRIs, CT scans, EKGs, and some other diagnostic tests)

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''Essential Health Benefits''[47]	Medicare Benefits[48]
''Preventive and wellness services and chronic disease management''	Abdominal Aortic Aneurysm Screening Bone Mass Measurement (Bone Density) Cardiovascular Screenings Colorectal Cancer Screenings Diabetes Screenings Diabetes Self-Management Training EKG Screening Eye Exams for People with Diabetes Flu Shots Foot Exams and Treatment Glaucoma Tests Hearing and Balance Exams Hepatitis B Shots HIV Screening Kidney Disease Education Services Mammograms (screening) Medical Nutrition Therapy Services Pap Tests and Pelvic Exams (includes clinical breast exam) Physical Exam (one-time ''Welcome to Medicare'' physical exam) Pneumococcal Shot Prostate Cancer Screenings Smoking Cessation
''Pediatric services, including oral and vision care''	NONE
Other benefits, as identified by the Secretary[49]	Clinical Research Studies Hospice Care

[47] These are the actual words in PPACA as to what is required, at a minimum, for inclusion in the ''essential health benefits package.''

[48] These are the actual words used in the Medicare & You 2010 Handbook to describe briefly the Medicare covered benefits, *available at* http://www.medicare.gov/Publications/Pubs/pdf/10050.pdf (last visited Dec. 3, 2010).

[49] PPACA § 1302 says, ''the Secretary shall define the essential health benefits, except that such benefits shall include at least the following general categories and the items and services covered within the categories'' (emphasis added). PHSA § 2715, added by PPACA § 1001, requires that information to consumers about their choices of products in the exchanges include a description of the coverage, including cost sharing for ''each of the categories of the essential health benefits described in subparagraphs (A) through (J) of section 1302(b)(1)'' and ''other benefits, as identified by the Secretary.''