July 30, 2020

VIA EMAIL

Deputy Administrator and Director Randy Pate
Center for Consumer Information and Insurance Oversight
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, D.C.

Re: Colorado Analysis of Essential Health Benefits and Infertility Coverage

Dear Director Pate:

During the 2020 legislative session, the Colorado State legislature passed, and the Governor signed, legislation clarifying the availability of infertility coverage under state regulated health insurance plans. The legislation (HB20-1158) requires issuers to provide coverage for the diagnosis and treatment for infertility and for standard preservation services. The coverage includes three completed oocyte retrievals with unlimited embryo transfers in accordance with the guidelines of the American Society for Reproductive Medicine.

As directed by HB20-1158, the Colorado Division of Insurance (Division) is submitting this determination that HB20-1158 does not constitute a new state mandate subject to state defrayal for the reasons set forth below. We request your confirmation of our determination within 60 days of the date of this letter.

Background

Under the federal rules implementing the Affordable Care Act (ACA), states are responsible for identifying which benefits are in addition to essential health benefits (EHBs). 45 C.F.R. § 155.170(a)(3). In making this determination with respect to the infertility coverage outlined in HB20-1158, Colorado has considered the federal guidance on what may or may not be considered a state mandate that is in addition to EHB.[1]

EHBs must be equal in scope to the benefits provided under a typical employer plan, and, under both federal and state rules, must cover at least the following ten general categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. As states are the primary entities providing oversight and enforcement of standards for insurance company marketing, premium

[1] CMS/CCIIO, "Frequently Asked Questions on Defrayal of State Additional Required Benefits," October 23, 2018. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQ-Defrayal-State-Benefits.pdf.

rates, and benefit design, states may enact legislation and issue interpretive regulations or sub-regulatory guidance to clarify EHBs.

When new benefits are mandated to comply with federal requirements, such as to provide benefits in each of the ten EHB categories, or to supplement an EHB category, they are not considered new benefits. Benefits mandated by state action after December 31, 2011 for purposes of compliance with new federal requirements do not require defrayal. The Department of Health and Humans Services (HHS) has identified requirements to provide benefits and services in each of the ten EHB categories, requirements to cover preventive services, requirements to comply with the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, and the removal of discriminatory age limits from existing benefits as examples of federal requirements that do not require defrayal. Changes to service delivery methods, provider types, cost sharing or reimbursement methods do not trigger the requirement for a state to defray the cost.

Section 1302(b)(4)(G) of the ACA require HHS to "periodically review" the EHB and assess whether enrollees are facing "any difficulty accessing needed services" and whether the EHB needs "to be modified or updated to account for changes in medical evidence or scientific advancement." Pursuant to Section 1302(b)(4)(H), HHS must then "periodically update" the EHB to "address any gaps in access to coverage or changes in the evidence base." HHS delegated the responsibility for implementing and enforcing the ACA's EHB requirements to states, including the obligation to periodically update the EHB to address changes in the evidence base. 45 C.F.R. §§ 156.100; 156.111.

Colorado's HB 20-1158 is an Update to Existing Coverage and Not a New Benefit Mandate

Colorado has existing mandates concerning the coverage of pregnancy-related benefits and services. Colorado Revised Statute Section 10-16-104(3) requires coverage for maternity care. Specifically, Section 10-16-104(3)(a)(I)(A), C.R.S., requires all subject sickness or accident insurance policies to insure against the expense of "normal pregnancy." Normal pregnancy is not defined in Colorado statutes or Division regulations; however, Colorado statute requires that all general provisions, terms, phrases and expressions, used in any statute, shall be liberally construed in order that the true intent and meaning of the general assembly may be fully carried out. C.R.S. § 2-4-212. Such broad language demonstrates the breadth of the legislative command. Here, HB20-1158 creates no new coverage or benefits, rather it clarifies the scope of normal pregnancy by recognizing that the term encompasses treatments that may be in furtherance of, or necessary for, a covered person to achieve a normal pregnancy. Thus, the phrase 'normal pregnancy' encompasses treatments necessary to achieve pregnancy. This clarification is consistent with the broad phrase selected by the original legislators in drafting the EHB. The fact that a statute may be applied in situations not expressly anticipated by the drafters does not demonstrate ambiguity.[2] "'It is ultimately the provisions of' those legislative commands 'rather than the principal concerns of the legislators'" which govern. [3]

[2] *Bostock v. Clayton County, Georgia,* 590 U.S. ___, 24 (2020) (citing *S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 499 (1985)).
[3] *Id*. (quoting *Oncale v. Sundowner Offshore Services, Inc.,* 523 U.S. 75, 79 (1998).

The clarification contained in HB 20-1158 is also necessary to keep Colorado's EHBs current with changes in medical evidence and scientific advancement. The 2017 Colorado benchmark plan, the state's current benchmark plan, provides coverage for infertility treatment. The Kaiser benchmark plan covers the following services, including X-ray and laboratory procedures: (a) Services for diagnosis and treatment of involuntary infertility; and (b) artificial insemination, except for donor semen, donor eggs and services related to their procurement and storage. While the Colorado benchmark plan excludes certain services and supplies other than artificial insemination (AI), it is important to note that IVF is no longer considered an experimental procedure and is the standard of infertility care for many patients. The American College of Obstetricians and Gynecologists recognize assisted reproductive technology and in vitro fertilization as treatments for infertility.[4] Given the evolution in infertility treatments, Colorado's EHB must be "modified or updated to account for changes in medical evidence or scientific advancement" and to reflect those "changes in the evidence base."

Without the services outlined in HB20-1158, treatment for infertility may be incomplete and, for some covered persons, rendered meaningless. HB20-1158 provides what may be the only effective infertility treatment for a covered person. For these reasons, IVF coverage is a clarification of existing maternity and obstetrical coverage, not a new mandate.

Colorado's HB20-1158 is Required to Comply with Federal Nondiscrimination Law

The clarification of coverage contained in HB 20-1158 is also necessary to comply with federal requirements related to nondiscrimination. As HHS has recognized, states are not required to defray the costs of benefits to bring their EHBs into compliance with federal law. *See* 45 C.F.R. § 155.170(a)(2).

According to federal rules, "[a]n insurer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions." 45 C.F.R. § 156.125(a). The state's benchmark plan may not include a discriminatory benefit design. 45 C.F.R. § 156.111(b)(2)(v). Notably, the states are primarily responsible for ensuring that its EHBs meet the ACA's nondiscrimination rules and provide EHB benefits for "diverse segments of the population, including women, children, persons with disabilities, and other groups." 45 C.F.R. § 156.111(b)(2)(iv); see also 42 U.S.C. § 18022(b)(4)(C). HHS has directed states that, when enforcing the ACA's nondiscrimination standards for EHB, "(l)imitations and exclusions are expected to be based on *clinical guidelines and medical evidence*…" (emphasis added). 80 Fed. Reg. 10750, 10823 (Feb. 27, 2015). To the extent that clinical guidelines and medical evidence support use of IVF over AI for treatment of infertility, then one could argue that excluding IVF but not AI from the benefit package violates the nondiscrimination rules.[5]

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[4] https://www.acog.org/patient-resources/faqs/gynecologic-problems/treating-infertility.

[5] This is especially true in light of the Supreme Court's decision in *Bostock v. Clayton County, Georgia*, in which the Court held that an employer who fires an individual merely for being gay or transgender violates Title VII's command that it is "unlawful . . . for an employer to fail or refuse to hire or to discharge any individual, or otherwise to discriminate against any individual with respect to his compensation, terms, conditions, or privileges of employment, because of such individual's … sex .." 590 U.S. ___, 4 (2020) (*citing* 78 Stat. 255, 42 U. S. C.

HHS actions related to prescription drug access are illustrative in this regard. In 2019, HHS "encourage(d) every health insurance plan to provide comprehensive coverage of MAT, even if the applicable EHB-benchmark plan does not require the inclusion of all four MAT drugs on a formulary…. As is the case for any EHB, issuers are expected to impose limitations and exclusions on the coverage of benefits to treat opioid use disorder, including the drugs used for MAT or any associated benefit such as counseling or drug screenings, based on clinical guidelines and medical evidence, and are expected to use reasonable medical management." 84 Fed. Reg. 17454, 17536 (Apr. 25, 2019). Similarly, HHS had informed QHP issuers that failure to cover a version of a drug that is "customarily prescribed" would constitute a discriminatory benefit design: "If an issuer refuses to cover a single tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regiment, we believe that, absent an appropriate reason for such refusal, such a plan design effectively discriminates against, or discourages enrollment by, individuals who would benefit from such innovative therapeutic options." 79 Fed. Reg. 70674, 70722 (Nov. 26, 2014).

In summary, for the reasons stated above, the Division believes that HB20-1158 concerning infertility coverage does not create a new state mandate requiring defrayal of any additional premium costs. We would appreciate your consideration and concurrence of our determination.

Kate Harris
Chief Deputy Commissioner
Life and Health Policy

Cc: Rebecca Bucchieri, CMS

§2000e–2(a)(1)). As noted by Justice Alito in his dissent, the same logic could be applied to the anti-discrimination provisions of the Affordable Care Act. *See* 590 U.S. ____, 87 (2020)(Alito, J., dissenting). Further, Colorado statute and Division Regulation generally prohibit discrimination based on sexual orientation (*see* 10-3-1104(1)(f)(III), C.R.S., 3 C.C.R. 702-4:4-2-62); and age (*see* 24-34-301(1), C.R.S.).