1) May health plans notify parents about sharing records in the registry by mail?

Yes. Although California Health and Safety Code Section 120440 (H&SC 120440) does not specify the method of notification, there are no other practical means besides mail for health plans to accomplish notification, as they often do not have direct contact with the patient.

2) May the regional registries notify parents by mail about sharing records in the registry?

Notification by mail is acceptable as described above. The responsibility to notify the parent belongs to the entity planning to disclose patient information to the registry. It would be problematic for registries to act as agents of providers or health plans in notifying parents because this would imply that confidential information had already been disclosed to the registry in violation of HIPAA and H&SC 120440 (e), which reads in part:

“A patient or a patient’s parent or guardian may refuse to permit record sharing. The health care provider administering immunization and any other agency possessing any patient or client information listed in subdivision (c), if planning to provide patient or client information to an immunization system, as described in subdivision (b), shall inform the patient or client, or the parent or guardian of the patient or client, of the following...”

However, if a public health department that operates a registry, because of its operation of a health clinic, for example, possesses patient or client information listed in H&SC 120440 (c), which includes name, address, and telephone number, the public health department could notify the child’s family and, if the family did not opt-out, include that information in the registry.

3) How many places can/should a disclosure notice come from? How often should notification occur?

Notification must be performed by any provider, health plan or agency planning to share information with an immunization registry before disclosing the information. As covered entities under HIPAA, it is prudent for health plans to implement and monitor notification for their own protection. The frequency of notification is up to each provider or plan.
4) What are the requirements for a letter of notification to parents?

- A font size of 12 point or larger is advisable for notification about the registry;
- A reading level of Sixth Grade or less;
- Availability in languages other than English: As a rule of thumb, use the federally proscribed Title VI threshold languages, those spoken by >5% of the Medi-Cal beneficiary population whose primary language is not English;
- Content requirements: The contents required are spelled out at H&SC 120440, including H&SC 120440 (e) (1)-(4):

“(1) The information listed in subdivision (c) may be shared with local health departments, and the State Department of Health Services. The health care provider or other agency shall provide the name and address of the department or departments with which the provider or other agency will share the information. (2) Any of the information shared with local health departments and the State Department of Health Services shall be treated as confidential medical information and shall be used only to share with each other, and, upon request, with health care providers, schools, child care facilities, family child care homes, WIC service providers, county welfare departments, foster care agencies, and health care plans. These providers, agencies, and institutions shall, in turn, treat the shared information as confidential, and shall use it only as described in subdivision (d). (3) The patient or client, or parent or guardian of the patient or client, has the right to examine any immunization-related information shared in this manner and to correct any errors in it. (4) The patient or client, or the parent or guardian of the patient or client, may refuse to allow this information to be shared in the manner described, or to receive immunization reminder notifications at any time, or both...”

The letter must describe the registry data elements listed in H&SC 120440 (c):

“The following information shall be subject to this subdivision: (1) The name of the patient or client and names of the parents or guardians of the patient or client. (2) Date of birth of the patient or client. (3) Types and dates of immunizations received by the patient or client. (4) Manufacturer and lot number for each immunization received. (5) Adverse reaction to immunizations received. (6) Other non-medical information necessary to establish the patient's or client's unique identity and record.
(7) Current address and telephone number of the patient or client and the parents or guardians of the patient or client.
(8) Patient's or client's gender.
(9) Patient's or client's place of birth.”

Reasons allowed for sharing are specified in subdivision H&SC 120440 (d):

“They shall use the information listed in subdivision (c) only for the following purposes:
(A) To provide immunization services to the patient or client, including issuing reminder notifications to patients or clients or their parents or guardians when immunizations are due.
(B) To provide or facilitate provision of third-party payer payments for immunizations.
(C) To compile and disseminate statistical information of immunization status on groups of patients or clients or populations in California, without identifying information for these patients or clients included in these groups or populations.
(D) In the case of health care providers only, as authorized by Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.”

…

(2)(C) In the case of health care plans, to facilitate payments to health care providers, to assess the immunization status of their clients, and to tabulate statistical information on the immunization status of groups of [de-identified] patients.”

The notice should specify the name and address of the registry in which the data will be entered and a generic list of the entities with which data may be shared. Sample notification letters that fulfill these requirements are available from DHS Immunization Branch.

5) When notifying by mail, what is considered a “reasonable time” to wait for a response?

This is not specified in the H&SC 120440. Health plans should seek guidance from their legal counsel. 30 days seems reasonable.

6) When notifying by mail, what are considered “reasonable means” to decline: Mail, regular or special; telephone, pay or toll-free; Internet; other? Also, what is required to verify parental refusal to share: signature, other?

Plans and providers should minimize barriers to record parental refusal. For example, parents offering refusal during a telephone call should not also be required to submit their refusal in writing. Toll calls, especially long-distance calls, and Internet responses may be too expensive for
indigent clients. Toll-free and local telephone calls are reasonable means, as is pre-paid mail. Internet reply is acceptable, but economical alternatives must be available in addition.

7) If a registry is operating as a covered entity instead of an exempt entity: -- does it need its providers to obtain a signed disclosure from parents?

No.

-- does it affect the sharing of records with other authorized partners such as Providers; Health plans; Schools; Childcare; WIC?

No.

8) The public health system is exempt under HIPAA for immunization registry-related activities. How does HIPAA apply to registry activities performed by entities that are legally authorized to use the registry, such as private or public health care providers or health plans?

Under the HIPAA Privacy Rule, state laws which provide for the conduct of public health surveillance or intervention, such as the immunization registry law, are not pre-empted. The immunization registry law controls providers’ and health plans’ disclosures to the registry and use of registry information. The registry statute is in some respects more stringent than the HIPAA Privacy Rule. H&SC 120440 specifies the procedure for disclosing information to the registry. H&SC 120440 also specifies which entities are authorized to access this information and for what purposes. In addition, immunization registry information should be protected in the same manner as other identifiable medical information which the health care entity has, meaning that the HIPAA privacy and security safeguards would apply to this immunization information.

9) How does each party’s status—as either a public health-exempt or a covered entity— affect written agreements between providers and registries?

Regardless of the HIPAA status of the parties, a written agreement between the registries and providers, such as a “trading partner agreement”, is advisable to clarify the nature of the agreement and specify confidentiality protections.
10) Does a health plan that operates in multiple registry regions need to arrange an MOU (written agreement) with each region? If so, do all MOUs need to be identically worded?

It is prudent to have a signed MOU or “trading partner agreement” between a health plan and each registry with which it does business. Having similar wording would be in everyone’s best interest.

11) Are there any HIPAA or other privacy implications raised by the extraction or transfer of public or private electronic billing data into the immunization registries?

Response combined with

12) One Medi-Cal managed care plan wants to create its multifunctional electronic version of the CHDP PM-160 billing form to avoid separate key entry of immunization registry data. Is this acceptable?

The relevant operating principle for transfer of information into immunization registries from other data systems is the HIPAA principle of “minimum necessary”. Only the data elements authorized in H&SC 120440 (c) should be transferred from other data systems into the registry.

Transfer of any data not listed in H&SC 120440 that is included in a billing or data entry system is not allowed under the HIPAA Privacy Rule. See 45 CFR 164.502(b)(1). Selective transfer of the subset of authorized data is allowed.

“(b) Standard: Minimum necessary. (1) Minimum necessary applies. When using or disclosing protected health information or when requesting protected health information from another covered entity, a covered entity must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.”

13) It has been proposed to add other childhood public health information, including TB skin testing, childhood lead testing, and newborn genetic screening results to the registry for access by physicians and the public health system. Could these results be added to the registry without a change in the Health and Safety Code?

No.

Would these additions alter the system’s exemption from HIPAA requirements?

No, but collection of the additional health data must be specifically authorized in statute, such as by an amendment to H&SC 120440.
14) If one parent consents to and the other declines participation, are their child’s immunization records allowed in the registry?

No. While this scenario is not addressed in H&SC 120440, every effort should be made to acknowledge refusal to participate.

15) If a parent refuses to share the record of a child covered by a Medi-Cal Managed Care Plan with the registry, does the registry have any right to the immunization information?

Response combined with

16) Does the public health system have authorized access to a child’s immunization record if a parent has refused sharing of the information in the registry? Does the California H&SC or Federal HIPAA either permit or forbid the sharing of immunization records between health care providers and public health departments but not other agencies, regardless of parental permission, for public health purposes (so-called ‘locked records’)?

(Revised 11/08) Yes. H&SC 120440 (e)(4) states that

After refusal, the patient's or client's physician may maintain access to this information for the purposes of patient care or protecting the public health. After refusal, the local health department and the State Department of Health Services may maintain access to this information for the purpose of protecting the public health pursuant to Sections 100325, 120140, and 120175, as well as Sections 2500 to 2643.20, inclusive, of Title 17 of the California Code of Regulations.

In addition:

--providers and health plans may share immunization records with each other for treatment, payment, and operations purposes.
--health care providers and plans may disclose health information to a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease and the conduct of public health surveillance, investigations, and interventions. [45 CFR 164.512 (b).]

17) Do providers need to indicate registry participation in their patient privacy statements in addition to a registry disclosure form?

Yes. However, many providers and plans already describe in their privacy statements the release of medical information to the public health system for public health activities. Such language would incorporate the release of patient data into the immunization registry. If such language currently exists in the privacy statement, amendment is not required.
If so, does a provider have to reissue a revised privacy statement to all patients?

Yes, if the privacy statement does not already contain permissive language as described above.

Is it sufficient to post a revised privacy statement in the office?

No.

18) Under HIPAA, are reminder postcards for immunizations allowed if specific vaccine names are absent (e.g., “Our records show that Johnny is due for shots”, not “Our records show that Johnny is due for a Hepatitis B shot”)?

Yes, as long as no confidential medical information is displayed.

19) May registries share their data with health plans for HEDIS assessments? Other QA efforts? Other reasons?

Sharing registry immunization data with plans for HEDIS reporting assists plans “to tabulate statistical information on the immunization status of groups of patients”, “to provide immunization services to the patient or client“, and “to assess the immunization status of their clients.” Thus, it falls within the permissible activities covered in the statute. Other quality assurance activities would have to be evaluated to see if they meet these or other uses authorized in H&SC 120440 (d).

20) How should protected patient health information provided by a registry for a health plan HEDIS audit be retained or stored? For how long? In what format (hard copy or electronic)?

There is no statutory standard for these issues. Answers should be determined by the rules and standards for individual health plans or by the Medi-Cal Managed Care Division. The general HIPAA standards for safeguarding protected health information apply to this immunization information, including privacy and security safeguards.

21) (Revised 11/08) What are the current provisions of H&SC 120440?

(Revised 11/08) The California law enabling the registry, H&SC 120440, is available at http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=120001-121000&file=120440
22) Can health plans have read-only access to the registry?

With regard to the Registry, health care plans are allowed to access information pertaining to a specific person to facilitate payments to health care providers, to assess the immunization status of their clients, and to tabulate statistical information on the immunization status of de-identified groups of patients (Health and Safety Code section 120440 (c) and (d)). However the Registry is only allowed to give health plans information upon a request for information pertaining to a specific person. This does not contemplate read-only access to the entire Registry.